IN THE UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

ROGER RHODES, ANTHONY SILVERS, and LEA ANNE SPRADLEN, On behalf of themselves and all others similarly situated,	)	Civil Action No. _____
Plaintiffs	)	**CLASS ACTION COMPLAINT**
	)	**JURY DEMAND**
v.	)	
RHODES TECHNOLOGIES, INC., RICHARD S. SACKLER, M.D., KATHE A. SACKLER, JONATHAN D. SACKLER, MORTIMER D.A. SACKLER, ILENE SACKLER LEFCOURT, BEVERLY SACKLER, THERESA SACKLER, DAVID A. SACKLER, ALLERGAN PLC F/K/A ACTAVIS PLC F/K/A ALLERGAN INC., ALLERGAN FINANCE LLC F/K/A ACTAVIS INC. F/K/A WATSON PHARMACEUTICALS, INC., ALLERGAN SALES, LLC, ALLERGAN USA, INC., WATSON LABORATORIES, INC., WARNER CHILCOTT COMPANY, LLC, ACTAVIS PHARMA, INC. F/K/A WATSON PHARMA, INC., ACTAVIS SOUTH ATLANTIC LLC, ACTAVIS ELIZABETH LLC, ACTAVIS MID ATLANTIC LLC, ACTAVIS TOTOWA LLC, ACTAVIS LLC, ACTAVIS KADIAN LLC, ACTAVIS LABORATORIES UT, INC., ACTAVIS LABORATORIES FL, INC., JOHNSON & JOHNSON, JANSSEN PHARMACEUTICALS, INC., NORAMCO, INC., ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. N/K/A JANSSEN PHARMACEUTICALS, INC., JANSSEN PHARMACEUTICA, INC. N/K/A JANSSEN	)	

PHARMACEUTICALS, INC., ENDO HEALTH	)
SOLUTIONS INC., ENDO PHARMACEUTICALS,	)
INC., PAR PHARMACEUTICAL, INC., PAR	)
PHARMACEUTICAL COMPANIES, INC. F/K/A	)
PAR PHARMACEUTICAL HOLDINGS, INC.,	)
TEVA PHARMACEUTICAL INDUSTRIES LTD.,	)
TEVA PHARMACEUTICALS USA, INC.,	)
CEPHALON, INC., MALLINCKRODT PLC,	)
MALLINCKRODT LLC, SPECGX LLC, KVK-TECH,	)
INC., AMNEAL PHARMACEUTICALS, LLC,	)
AMNEAL PHARMACEUTICALS, INC., IMPAX	)
LABORATORIES, LLC, AMNEAL	)
PHARMACEUTICALS OF NEW YORK LLC	)
	)
Defendants.	)

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I. PARTIES

A. PLAINTIFFS

1. Plaintiffs, Roger Rhodes, Anthony Silvers and Lea Anne Spradlen are citizens and residents of Davidson, Unicoi and Greene Counties in Tennessee. The Plaintiff's purchases occurred in Tennessee. Specifically, Roger Rhodes purchases occurred in Davidson County, Tennessee through a legally obtained prescription for opioids. Mr. Rhodes paid in cash and/or an insurance co-payment for the opioid medication. All Plaintiffs paid in cash or an insurance co-payment for their opioid medication.

2. The Defendants wrongful misrepresentations are the direct cause of all Plaintiffs and Plaintiff Class economic loss since they would not have bought the opioid drug had they known of the addiction propensities. All Plaintiffs and Plaintiff Class are purchasers of legally prescribed opioids. The retail supply chain is simple. Defendants sell to distributors who sell to pharmacies who sell to Plaintiffs and Plaintiff Class. All Plaintiffs and Plaintiff Class seek to recover the money they spent purchasing prescription opioids.

3. **According to the Centers for Disease Control and Prevention:** Table 1. Total number and rate of opioid prescriptions dispensed, United States, 2006-2017. The instant case includes thirty-one states and/or jurisdictions.

Year	Total Number of Prescriptions	Prescribing Rate Per 100 Persons
2006	215,917,663	72.4

Year	Total Number of Prescriptions	Prescribing Rate Per 100 Persons
2007	228,543,773	75.9
2008	237,860,213	78.2
2009	243,738,090	79.5
2010	251,088,904	81.2
2011	252,167,963	80.9
2012	255,207,954	81.3
2013	247,090,443	78.1
2014	240,993,021	75.6
2015	226,819,924	70.6
2016	214,881,622	66.5
2017	191,218,272	58.7

B. DEFENDANTS AND NON-SUED CO-CONSPIRATORS

4. At all relevant times, the Defendants and non-sued co-conspirators, each of whom is defined below, have packaged, distributed, supplied, sold, placed into the stream of commerce, labeled, described, marketed, advertised, promoted or purported to inform prescribers and users regarding the benefits and risks associated with the use of prescription opioid drugs.

5. PURDUE PHARMA L.P. ("PPL") is a limited partnership organized under the laws of

Delaware with its principal place of business in Stamford, Connecticut and is a non-sued co-conspirator.

6. PURDUE PHARMA INC. ("PPI") is a New York corporation with its principal place of business in Stamford, Connecticut and is a non-sued co-conspirator.

7. THE PURDUE FREDERICK COMPANY, INC. ("PFC") is a New York corporation with its principal place of business in Stamford, Connecticut and is a non-sued co-conspirator.

8. Defendant RHODES PHARMACEUTICALS L.P. is a limited partnership organized under the laws of Delaware with its principal place of business in Coventry, Rhode Island. Rhodes Pharmaceuticals L.P. has one general partner, Rhodes Pharmaceuticals, Inc.; and one limited partner, Coventry Technologies L.P., which holds Rhodes Pharmaceuticals, L.P.'s shares. Coventry Technologies L.P. is a Delaware limited partnership with its principal place of business in Stamford, Connecticut. Its general partner is Purdue Pharma Inc. Rhodes Technologies Inc. is a corporation organized under the laws of Delaware with its principal place of business in Coventry, Rhode Island. Rhodes Technologies is a Delaware general partnership with its principal place of business in Coventry, Rhode Island. Rhodes Technologies Inc. is the general partner of Rhodes Technologies and is a subsidiary of Purdue Pharma, L.P. (Rhodes Technologies and Rhodes Pharmaceuticals are collectively referred to as "Rhodes"). Rhodes manufactures and distributes generic opioids, including authorized generic versions of OxyContin and Butrans. Rhodes Technologies also manufacturers the active pharmaceutical ingredient in drugs including Purdue's OxyContin. Among the drug products manufactured by Rhodes is buprenorphine, a drug used to treat opioid

dependence.

9. Although it is registered as a separate corporate entity than Purdue Pharma L.P., Purdue Pharma, Inc., and The Purdue Frederick Company Inc. (collectively, "Purdue"), a former senior manager at Purdue described Rhodes Pharmaceuticals, L.P., as "set up as a 'landing pad' for the Sackler family in 2007, to prepare for the possibility that they would need to start afresh following the crisis then engulfing OxyContin." Further, reporting by the *Financial Times* revealed that a 2017 manual showed that Rhodes and Purdue used the same employee handbook, and employees reported that "little distinction is made internally between the two companies." Together, Rhodes and Purdue accounted for 14.4 million opioid prescriptions in the United States in 2016.

10. PPL, PPI, PFC, Rhodes and their DEA registrant subsidiaries and affiliates (collectively, "Purdue Companies") are engaged in the manufacture, promotion, distribution, and sale of opioids nationally and in the states which are included in this complaint, including the following products:

OxyContin/Oxycodone hydrochloride, extended release/Schedule[30]
MS Contin/ Morphine sulfate, extended release/Schedule II
Dilaudid/ Hydromorphone hydrochloride/Schedule II
Dilaudid- HP/ Hydromorphone hydrochloride/Schedule II
Butrans/ Buprenorphine/Schedule III
Hysingla ER/ Hydrocodone bitrate/Schedule II
Targiniq ER/ Hydrocodone bitrate/ Schedule II

11. Purdue made thousands of payments to physicians nationwide ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, but in fact to deceptively promote

and maximize the use of opioids.

12. OxyContin is Purdue's largest-selling opioid. Since 2009, Purdue's national annual sales of OxyContin have fluctuated between $2.47 billion and $3.1 billion, up four-fold from 2006 sales of $800 million. OxyContin constitutes roughly 30% of the entire market for analgesic drugs (*i.e.*, painkillers). Sales of OxyContin (launched in 1996) went from a mere $49 million in its first full year on the market to $1.6 billion in 2002.

13. In 2007, Purdue settled criminal and civil charges against it for misbranding OxyContin and agreed to pay the United States $635 million—at the time, one of the largest settlements with a drug company for marketing misconduct. None of this stopped Purdue. In fact, Purdue continued to create the false perception that opioids were safe and effective for long term use, even after being caught, by using unbranded marketing methods to circumvent the system. In short, Purdue paid the fine when caught and then continued business as usual, deceptively marketing and selling billions of dollars of opioids each year.

14. Defendant **RICHARD S. SACKLER, M.D**., is a natural person residing in Travis County, Texas. He has served as a member of the Board of Directors of Purdue and Purdue-related entities since the 1990s. Richard Sackler was President of Purdue Pharma from 1999 to 2003 and Co-Chairman in 2003 through 2014. Upon information and belief, Sackler joined Purdue in 1971 as an assistant to his father, Dr. Raymond Sackler who was then President of Purdue. He served as head of Purdue's Marketing and Research & Development Departments. From 1995-2003, Defendant Richard Sackler oversaw the launch of OxyContin. Richard Sackler, upon information and belief, has long been the beneficiary of an ownership interest in Purdue and Rhodes, and

continues to hold such an ownership interest. Through his decisions and directives, Richard Sackler knowingly caused and approved the promotion and sales of Purdue and Rhodes opioids. Richard Sackler is the listed inventor on a number of patents assigned to Purdue or Rhodes, including U.S. Patent 9,3861,628, *Buprenorphine-Wafer for Drug Substitution Therapy* (January 9, 2018), a patent issued, inter alia, to Sackler and assigned by Sackler and his co-inventors to Rhodes covering a drug for "drug substitution therapy in drug-dependent human subjects." In other words, having played no small part in causing the opioid epidemic, Richard Sackler, through his companies, is poised to profit off of its abatement.

15. Defendant **KATHE A. SACKLER** is a natural person residing in Fairfield County, Connecticut. Kathe Sackler began serving as Senior Vice President of Purdue by 2000. She resigned from her position in or about 2003. She has served as a member of the Board of Directors of Purdue and Purdue-related entities and on various Board committees since the 1990s and was instrumental in Purdue's "Project Tango."

16. Defendant **JONATHAN D. SACKLER** is a natural person residing in Fairfield County, Connecticut. Jonathan Sackler served as Senior Vice President of Purdue by 2000, until stepping down in 2003. He has served as a member of the Board of Directors of Purdue and Purdue-related entities since the 1990s.

17. Defendant **MORTIMER D.A. SACKLER** is a natural person residing in New York County, New York. He has served as a member of the Board of Directors of Purdue and Purdue-related entities since the 1990s.

18. Defendant **ILENE SACKLER LEFCOURT** is a natural person residing in New York County, New York. She has served as a member of the Board of Directors of Purdue

and Purdue-related entities since the 1990s.

19. Defendant **BEVERLY SACKLER** is a natural person residing in Fairfield County, Connecticut. She has served as a member of the Board of Directors of Purdue and Purdue-related entities since the 1990s.

20. Defendant **THERESA SACKLER** is a natural person residing in New York County, New York. She has served as a member of the Board of Directors of Purdue and Purdue- related entities since the 1990s.

21. Defendant **DAVID A. SACKLER** is a natural person residing in New York County, New York. He has served as a member of the Board of Directors of Purdue and Purdue-related entities since 2012.

22. Collectively, Defendants Richard, Kathe, Jonathan, Mortimer D.A, Ilene, Beverly, Theresa and David Sackler are referred to as the "**Sackler Family**" or the "**Sackler Defendants**." Together, the Sackler Defendants, upon information and belief, were not only aware of, but approved and exercised control over Purdue's deceptive marketing.

23. For example, in a deposition taken for prior litigation, a Purdue legal secretary named Maureen Sara testified that in late 1999, she sent a memorandum to the Sacklers, including Richard Sackler, about what she had learned on the internet about "crushing the tablets [of OxyContin], taking the coating off, cooking it up. Shooting or snorting it."

24. According to Barry Meier's book Pain Killer, in early 2001, Purdue met with the DEA, which was starting to raise alarms over OxyContin overdoses. Defendant Sackler participated in this meeting and defended OxyContin as an extremely good drug.

According to the book, the head of the DEA's Office of Diversion Control leaned across to Defendant Sackler and stated: "People are dying. Do you understand that?" Evidently Richard Sackler either did not understand or care, for Purdue did nothing to rein in Purdue's misleading promotion of OxyContin. And, internally, Richard Sackler chose to stigmatize and blame those who became addicted or began to abuse opioids. In February of 2001, he wrote that: "we have to hammer on the abusers in every way possible. They are the culprits and the problem. They are reckless criminals."

25. Federal prosecutors came to suspect, however, that Purdue and certain of its executives were the criminals. In 2003, while a criminal investigation into Purdue and three other executives was underway, the Sackler Defendants all quietly resigned from their management positions. Nevertheless, the Sackler Defendants, upon information and belief, remained actively involved in Purdue's affairs and would also have been aware of deceptive marketing in their capacity as a board members at all relevant times. This involvement is detailed in internal company documents obtained by the Massachusetts Attorney General, parts of which were made public in *Commonwealth of Mass. v. Purdue Pharma L.P., et al.,* C.A. No. 1884-cv-01808 (BLS2), First Amended Complaint, Complete Unredacted Corrected Version for the Public File Submitted According to Court Order January 31, 2019 (Mass. Super. Ct. Jan. 31, 2019) (hereinafter, the "MA AG Complaint"). For example, according to the MA AG Complaint, internal documents show that the Sackler Defendants contemplated selling Purdue after its criminal plea in 2007 and other strategies to allow them to "distribute more free cash flow" to themselves."

26. As another example, Purdue's Board, while the Sackler Defendants were members, voted

to approve a criminal guilty plea by their company, including an Agreed Statement Of Facts admitting, in 2007, that, for more than six years, supervisors and employees intentionally deceived doctors about OxyContin: "Beginning on or about December 12, 1995, and continuing until on or about June 30, 2000, Purdue supervisors and employees, with the intent to defraud or mislead, marketed and promoted OxyContin as less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medications." Purdue's Board, while the Sackler Defendants were members, also voted to enter a Corporate Integrity Agreement with the United States. The Sackler Defendants each certified in writing to the U.S. government that he or she had read and understood the rules under that Agreement, including requirements to ensure that Purdue did not deceive doctors and patients again and to report any deception.

27. Yet, even after their company pled guilty to criminal charges, the Sackler Defendants still failed to follow the rules. For example, the Sacklers received reports that Purdue continued to mail out thousands of deceptive marketing materials in the first half of 2007 alone, with the single most-distributed material being volume #1 of Purdue's "Focused and Customized Education Topic Selections in Pain Management" (FACETS), which falsely claimed that physical dependence on opioids is not dangerous and instead improves patients' "quality of life." Internal documents illustrate the detailed information provided the Sackler Defendants concerning, for example, the hiring of sales representatives, the reports of concern the company received, and the "Region Zero" prescribers identified, internally, as suspicious.

28. From the time Purdue first developed OxyContin, the Sackler Defendants were focused

on sales. Richard Sackler had grand ambitions for Purdue; according to a long-time Purdue sales representative, "Richard really wanted Purdue to be big—I mean really big." At the OxyContin launch party, Richard Sackler spoke as the Senior Vice President responsible for sales, and asking his listeners to envision natural disasters, went on to say: "the launch of OxyContin Tablets will be followed by a blizzard of prescriptions that will bury the competition. The prescription blizzard will be so deep, dense, and white...." When sales appeared to slow, or did not meet their expectations in later years, the Sackler Defendants expressed concern and looked for way to increase their sales (and by extension, the volume and dose of opioids being prescribed and used). For example, internal correspondence from 2011 reveals Jonathan Sackler writing to John Stewart concerning sales that "this is starting to look ugly" and they needed to "talk," after which Stewart and the sales team planned a response and to set up a meeting with Jonathan. Similarly, in internal e-mails concerning OxyContin prescriptions, in 2008, Kathe asked for information on "pressures" and "quantification of their negative impact on projected sales." In 2012, Jonathan Sackler pressed Sales VP Russell Gasdia for periodic updates on sales. Richard Sackler was so deeply involved he even planned to go into the field with a sales representative. So intrusive was his involvement that an internal e-mail about his behavior reads: "Anything you can do to reduce the direct contact of Richard into the organization is appreciated." During a deposition this past March, Richard Sackler was presented with numerous emails showing how often he asked staff for sales data. Yet, when asked if he ever requested data on OxyContin abuse or overdose rates, he responded, "I don't recall that."

29. This detailed attention and care given sales and profits contrasted sharply, as explained

above, with the approach to addressing addiction, abuse, and diversion. For example, when Butrans sales were perceived as too low, internal documents described in the reveal that Richard Sackler wrote: "This is bad." By contrast, when informed of 59 deaths from OxyContin in a single state, Richard Sackler wrote: "This is not too bad" and further explained that: "It could have been far worse."

30. Kathe Sackler did pay close attention to opioid addiction, for profit, as part of a secret "Project Tango" which considered expanding Purdue's business into addiction treatment. In connection with "Project Tango," internal documents received by Kathe Sackler stated, "Pain treatment and addiction are naturally linked." A confidential presentation made as part of Project Tango highlighted, for example, the "[l]arge unmet need for vulnerable, underserved and stigmatized patient population." Yet, Purdue continued to press its sales tactics.

31. According to internal documents, from the 2007 criminal convictions until 2018 alone, the Board, with the Sackler Defendants as members, voted to pay to out more than four billion dollars that would go to the Sackler family. Meanwhile, media reports describe Purdue as considering a bankruptcy filing. In the wake of the 2007 guilty plea and Corporate Integrity Agreement, a 2007 settlement with state attorneys general, and more recent lawsuits by state and local governments, as well as other plaintiffs, the Sackler Defendants should, upon information and belief, have anticipated the liability Purdue faced at the time they voted to take money out of the company.

32. Defendant **ALLERGAN PLC** (f/k/a Actavis plc, f/k/a Allergan, Inc.) is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland, and its administrative headquarters and all executive officers located in Madison, New

Jersey. In October 2012, the Actavis Group was acquired by Watson Pharmaceuticals, Inc., and the combined company changed its name to Actavis, Inc. as of January 2013, and then to Actavis plc in October 2013. In October 2013, Actavis plc (n/k/a Allergan plc) acquired Warner Chilcott plc pursuant to a transaction agreement dated May 19, 2013. Actavis plc (n/k/a Allergan plc) was established to facilitate the business combination between Actavis, Inc. (n/k/a Allergan Finance, LLC) and Warner Chilcott plc. Following the consummation of the October 1, 2013 acquisition, Actavis, Inc. (n/k/a Allergan Finance, LLC Inc.) and Warner Chilcott plc became wholly-owned subsidiaries of Actavis plc (n/k/a Allergan plc). Pursuant to the transaction, each of Actavis, Inc.'s common shares was converted into one Actavis plc share. Further, Actavis plc (n/k/a Allergan plc) was the "successor issuer" to Actavis, Inc. and Warner Chilcott. Actavis plc acquired Allergan, Inc. in March 2015, and the combined company thereafter changed its name to Allergan plc.

33. The transaction that created Actavis plc converted each share of Actavis Inc.'s Class A common shares into one Actavis plc Ordinary Share. See City of Chicago v. Purdue Pharma L.P., et al. (N.D. Ill. 2015), No. 14-4361, 2015 WL 2208423, at *7. Actavis Inc. and Actavis plc had the same corporate headquarters both before and after the merger; Actavis plc had the same website as Actavis Inc.; and, Actavis plc maintained all of Actavis Inc.'s officers in the same positions. See id. Actavis plc's SEC filings explained that "references throughout to 'we,' 'our,' 'us,' the 'Company' or 'Actavis' refer interchangeably to Watson Pharmaceuticals, Inc., Actavis, Inc., and Actavis plc depending on the date." See City of Chicago v. Purdue Pharma L.P., et al. (N.D. Ill. 2015), No. 14-4361, 2015 WL 2208423, at *7.

34. Defendant **ALLERGAN FINANCE, LLC** (f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.) is a limited liability company incorporated in Nevada and headquartered in Madison, New Jersey. Allergan Finance, LLC is a wholly owned subsidiary of defendant Allergan plc. In 2008, Actavis, Inc. (n/k/a Allergan Finance, LLC), acquired the opioid Kadian through its subsidiary, Actavis Elizabeth LLC, which had been the contract manufacturer of Kadian since 2005. Since 2008, Kadian's label has identified the following entities as the manufacturer or distributor of Kadian: Actavis Elizabeth LLC, Actavis Kadian LLC, Actavis Pharma, Inc., and Allergan USA, Inc. Currently, Allergan USA, Inc. is contracted with UPS SCS, Inc. to distribute Kadian on its behalf.

35. Defendant **ALLERGAN SALES, LLC** is incorporated in Delaware and headquartered in Irvine, California. Allergan Sales, LLC is the current New Drug Application ("NDA") holder for Kadian, and in 2016, Allergan Sales, LLC held the Abbreviated New Drug Applications ("ANDAs") for Norco.32 Allergan Sales, LLC is the wholly-owned subsidiary of Allergan plc.

36. Defendant **ALLERGAN USA, INC**. is incorporated in Delaware and headquartered in Madison, New Jersey. Allergan USA, Inc. is currently responsible for Norco and Kadian sales. Allergan USA, Inc. is a wholly-owned subsidiary of Allergan plc.

37. Defendant **WATSON LABORATORIES, INC.** is a Nevada corporation with its principal place of business in Corona, California. Watson Laboratories, Inc. was sold to Teva Pharmaceutical Industries Ltd. as part of Allergan plc's 2016 sale of its generic businesses to Teva. Prior to the sale, Watson Laboratories, Inc. was a direct subsidiary of Actavis, Inc., (n/k/a Allergan Finance, LLC). Between 2000 and 2015, Watson

Laboratories, Inc. held the ANDAs for Norco and was the manufacturer of the drug. Watson Laboratories, Inc. was also the ANDA holder of various generic opioids.

38. Defendant **WARNER CHILCOTT COMPANY, LLC** is a limited liability company incorporated in Puerto Rico. Since 2015, Warner Chilcott Company, LLC has been the manufacturer of Norco. Warner Chilcott Company, LLC was a subsidiary of Warner Chilcott plc until Warner Chilcott plc became a wholly owned subsidiary of Allergan plc in 2013. Warner Chilcott Company LLC was sold to Teva Pharmaceutical Industries Ltd. as part of Allergan plc's 2016 sale of its generic businesses to Teva.

39. Defendant **ACTAVIS PHARMA, INC.** (f/k/a Watson Pharma, Inc.) is registered to do business with the West Virginia Secretary of State as a Delaware corporation with its principal place of business in New Jersey. Actavis Pharma, Inc. (f/k/a Watson Pharma, Inc.) was previously responsible for sales of Kadian and Norco. Actavis Pharma, Inc. was sold to Teva Pharmaceutical Industries Ltd. as part of Allergan plc's 2016 sale of its generic businesses to Teva.

40. Defendant **ACTAVIS SOUTH ATLANTIC LLC** is a Delaware limited liability company with its principal place of business in Sunrise, Florida. Actavis South Atlantic LLC was listed as the ANDA holder for oxymorphone and fentanyl transdermal. Actavis South Atlantic LLC was sold to Teva Pharmaceutical Industries Ltd. as part of Allergan plc's 2016 sale of its generic businesses to Teva.

41. Defendant **ACTAVIS ELIZABETH LLC** is a Delaware limited liability company with its principal place of business in Elizabeth, New Jersey. From December 19, 2005, until it purchased the medication in December 2008, Actavis Elizabeth LLC served as the contract manufacturer of Kadian for Alpharma. Actavis Elizabeth LLC held the NDA

for Kadian from 2008 to 2013. Actavis Elizabeth LLC was also the holder of ANDAs for the following Schedule II opioid products: oxycodone/acetaminophen; homatropine methylbromide/hydrocodone bitartrate; morphine sulfate capsule; morphine sulfate tablet; oxycodone/hydrochloride tablet; oxycodone/ibuprofen; and oxymorphone tablet. Actavis Elizabeth LLC was sold to Teva Pharmaceutical Industries Ltd. as part of Allergan plc's 2016 sale of its generic businesses to Teva.

42. Defendant **ACTAVIS MID ATLANTIC LLC** is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. Actavis Mid Atlantic LLC has held the ANDA for homatropine methylbromide/hydrocodone bitartrate. Actavis Mid Atlantic LLC was sold to Teva Pharmaceutical Industries Ltd. as part of Allergan plc's 2016 sale of its generic businesses to Teva.

43. Defendant **ACTAVIS TOTOWA LLC** is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. Actavis Totowa LLC has held the ANDAs for the following Schedule II opioid products: oxycodone/acetaminophen; homatropine methylbromide; oxycodone/hydrochloride.

44. Defendant **ACTAVIS LLC** is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. Defendants Actavis South Atlantic LLC, Actavis Elizabeth LLC, Actavis Mid Atlantic LLC, and Actavis Totowa LLC were all direct subsidiaries of Actavis LLC, which was an indirect subsidiary of defendant Watson Laboratories, Inc. Watson Laboratories, Inc., in turn, was a direct subsidiary of Actavis, Inc. (n/k/a Allergan Finance, LLC). Actavis LLC was sold to Teva Pharmaceutical Industries Ltd. as part of Allergan plc's 2016 sale of its generic businesses to Teva.

45. Defendant **ACTAVIS KADIAN LLC** is a Delaware limited liability company with its principal place of business in Morristown, New Jersey. Actavis Kadian LLC has been identified on Kadian's label as a manufacturer or distributor of Kadian. Actavis Kadian LLC was sold to Teva Pharmaceutical Industries Ltd. as part of Allergan plc's 2016 sale of its generic businesses to Teva.

46. Defendant **ACTAVIS LABORATORIES UT, INC**. (f/k/a Watson Laboratories, Inc.-Salt Lake City) is a Delaware limited liability company with its principal place of business in Salt Lake City, Utah. Actavis Laboratories UT, Inc. was the Kadian NDA holder from 2013 to 2016 and was listed as the NDA holder for morphine sulfate capsule. Actavis Laboratories UT, Inc. was sold to Teva Pharmaceutical Industries Limited as part of Allergan plc's 2016 sale of its generic businesses to Teva. Prior to the sale, Actavis Laboratories UT, Inc. was a direct subsidiary of Actavis, Inc. (n/k/a Allergan Finance, LLC).

47. Defendant **ACTAVIS LABORATORIES FL, INC.** (f/k/a Watson Laboratories, Inc.-Florida) is a Florida limited liability company with its principal place of business in Davie, Florida. Actavis Laboratories FL, Inc. was a Norco ANDA holder in 2015 and was the ANDA holder of the following Schedule II opioid products: hydrocodone/acetaminophen; hydrocodone/ibuprofen; oxycodone/aspirin; and hydromorphone tablet. Actavis Laboratories FL, Inc. was sold to Teva Pharmaceutical Industries Ltd. as part of Allergan plc's 2016 sale of its generic businesses to Teva. Prior to the sale, Actavis Laboratories FL, Inc. was a direct subsidiary of Andrx Corporation, which was a direct subsidiary of Actavis, Inc. (n/k/a Allergan Finance, LLC). Andrx Corporation was transferred to Teva as part of the 2016 sale.

48. Each of these defendants and entities currently is or was previously owned by Defendant Allergan plc, which uses them to market and sell its drugs in the United States. Collectively, these defendants and entities, and their DEA registrant subsidiaries and affiliates that manufacture, promote, distribute, and sell prescription opioids, are referred to as "**Actavis**."

49. Actavis has engaged in the manufacture, promotion, distribution, and sale of the branded and generic prescription opioid drugs sold throughout the country, including into West Virginia and Cabell County.

50. Actavis manufactures or has manufactured the following drugs as well as generic versions of Kadian, Duragesic, and Opana in the United States:

> Kadian/Morphine sulfate, extended release/Schedule II
> Norco/Hydrocodone bitartate and acetaminophen/Schedule II

51. Defendant **JOHNSON & JOHNSON** ("J&J") is a New Jersey corporation with its principal place of business in New Brunswick, New Jersey.

52. Defendant **JANSSEN PHARMACEUTICALS, INC.** ("Janssen Pharmaceuticals") is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly-owned subsidiary of J&J. J&J corresponds with the FDA regarding Janssen's products. Janssen Pharmaceuticals, Inc. formerly was known as Ortho-McNeil-Janssen Pharmaceuticals, Inc., which in turn was formerly known as Janssen Pharmaceutica, Inc.

53. Defendant **NORAMCO, INC.** ("Noramco") is a Delaware company headquartered in Wilmington, Delaware with offices in Athens, Georgia and Schaffhausen, Switzerland.

Noramco was a wholly owned subsidiary of J&J and its manufacturer of active pharmaceutical ingredients until July 2016 when J&J sold its interests to SK Capital Partners LP, a limited partnership incorporated in Delaware.

54. Defendant **ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC**. ("OMP"), now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey.

55. Defendant **JANSSEN PHARMACEUTICA, INC**. ("Janssen Pharmaceutica"), now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey.

56. Defendant, **TASMANIAN ALKALOIDS PTY LTD**. ("Tasmanian Alkaloids") is an Australian private company based in Westbury, Australia and incorporated in Tasmania, Australia. Tasmanian Alkaloids Pty Ltd. was a wholly owned subsidiary of J&J until July 2016 when J&J sold its interests to SK Capital Partners LP, a limited partnership incorporated in Delaware.

57. J&J, Janssen Pharmaceuticals, OMP, Janssen Pharmaceutica, Noramco, and Tasmanian Alkaloids Pty Ltd. (collectively, "**Janssen**") are or have been engaged in the manufacture, promotion, distribution, and sale of opioids nationally. Among the drugs Janssen manufactures or manufactured are the following:

> Duragesic/Fentanyl/Schedule II
>
> Nucynta[33]/Tapentadol hydrochloride, immediate release/Schedule II
>
> Nucynta ER/Tapentadol hydrochloride, extended release/Schedule II

58. Janssen made thousands of payments to physicians nationwide, ostensibly for activities

including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, but in fact to deceptively promote and maximize the use of opioids. Together, Nucynta and Nucynta ER accounted for $172 million in sales in 2014. Prior to 2009, Duragesic accounted for at least $1 billion in annual sales.

59. Information from the U.S. Department of Justice's Office of the Inspector General shows that J&J made payments to prescribers, but does not indicate which drug was being promoted when J&J made these payments.

60. Prior to 2016, Janssen also had a global Active Pharmaceutical Ingredients (API) Manufacturing Network for opiate analgesics and antagonists and was among the largest narcotic API suppliers in the United States. Tasmanian Alkaloids created, manufactured and patented a new, more potent strand of poppy (high thebaine) and delivered it via intercompany transfer to Noramco. Part of the J&J Family of Companies, Noramco and Tasmanian Alkaloids are "sister companies" [34] operating in a backward integration model to control the supply chain of opioid materials for production of "high-purity controlled substances."[35] Noramco's product portfolio included Oxycodone (OxyContin, Percocet, Roxicodone), Hydrocodone (Vicodin, Lortab), Morphine (MS Contin, Embeda) in addition to Naloxone (Narcan, Exalgo) for overdose and abuse.[36] Noramco supplied Teva, Endo, Purdue, and Mallinckrodt. In 2015, 80% of Normaco's sales were via long-term supply agreements and/or majority controlled substance share with all 7 of the top U.S. generic companies. [37] Noramco steadily gained US market share and capitalized on key brand to generic switches.

Janssen, like many other companies, has a corporate code of conduct, which clarifies the organization's mission, values and principles. Janssen's employees are required to read, understand and follow its Code of Conduct for Health Care Compliance. J&J imposes this code of conduct on Janssen as a pharmaceutical subsidiary of J&J. Documents posted on J&J's and Janssen's websites confirm J&J's control of the development and marketing of opioids by Janssen. Janssen's website "Ethical Code for the Conduct of Research and Development," names only J&J and does not mention Janssen anywhere within the document. The "Ethical Code for the Conduct of Research and Development" posted on the Janssen website is J&J's company-wide Ethical Code, which it requires all of its subsidiaries to follow.

61. The "Every Day Health Care Compliance Code of Conduct" posted on Janssen's website is a J&J company-wide document that describes Janssen as one of the "Pharmaceutical Companies of J&J" and as one of the "J&J Pharmaceutical Affiliates." It governs how "[a]ll employees of J&J Pharmaceutical Affiliates," including those of Janssen, "market, sell, promote, research, develop, inform and advertise J&J Pharmaceutical Affiliates' products." All Janssen officers, directors, employees, sales associates must certify that they have "read, understood and will abide by" the code. The code governs all of the forms of marketing at issue in this case.

62. Defendant **ENDO HEALTH SOLUTIONS INC.** ("EHS") is a Delaware corporation with its principal place of business in Malvern, Pennsylvania.

63. Defendant **ENDO PHARMACEUTICALS, INC**. ("EPI") is a wholly owned subsidiary of EHS and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania.

64. Defendant **PAR PHARMACEUTICAL, INC**. is a Delaware corporation with its principal place of business located in Chestnut Ridge, New York. Par Pharmaceutical, Inc. is a wholly owned subsidiary of Par Pharmaceutical Companies, Inc. f/k/a Par Pharmaceutical Holdings, Inc. Defendant Par Pharmaceuticals Companies, Inc. is a Delaware corporation with its principal place of business located in Chestnut Ridge, New York (Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc. collectively, "Par Pharmaceutical"). Par Pharmaceutical was acquired by Endo International plc in September 2015 and is an operating company of Endo International plc. EHS, EPI, and Par Pharmaceutical, and their DEA registrant subsidiaries and affiliates (collectively, "**Endo**") manufacture opioids sold nationally, and in Huntington. Among the drugs Endo manufactures or manufactured are the following:

Opana ER/Oxymorphone hydrochloride, extended release/Schedule II
Opana/Oxymorphone hydrochloride/Schedule II
Percodan/Oxymorphone hydrochloride and aspirin/Schedule II
Percocet/Oxymorphone hydrochloride and acetaminophen/Schedule II
Generic/Oxycodone/Schedule II
Generic/Oxymorphone/Schedule II
Generic/Hydromorphone/Schedule II
Generic/Hydrocodone/Schedule II

65. Endo made thousands of payments to physicians nationwide ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, but in fact to deceptively promote and maximize the use of opioids.

66. Opioids made up roughly $403 million of Endo's overall revenues of $3 billion in 2012, accounting for over 10% of Endo's total revenue; Opana ER yielded revenue of $1.15

billion from 2010 to 2013. Endo also manufactures and sells generic opioids, both directly and through its subsidiaries, Par Pharmaceutical and Qualitest Pharmaceuticals, Inc., including generic oxycodone, oxymorphone, hydromorphone, and hydrocodone products.

67. The Food and Drug Administration requested that Endo remove Opana ER from the market in June 2017. The FDA relied on post-marketing data in reaching its conclusion based on risk of abuse.

68. Defendant **TEVA PHARMACEUTICALS USA, INC**. ("Teva USA") is a Delaware corporation with its principal place of business in North Wales, Pennsylvania. Teva USA was in the business of selling generic opioids, including a generic form of OxyContin from 2005 to 2009. Teva USA is a wholly owned subsidiary of Defendant **Teva Pharmaceutical Industries, Ltd**. ("Teva Ltd."), an Israeli corporation (collectively "Teva").

69. Defendant **CEPHALON, INC.** is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. In 2011, Teva Ltd. acquired Cephalon, Inc. In 2016, Teva Ltd acquired Allergan plc's generic businesses.

70. Teva USA and Cephalon, Inc. and their DEA registrant subsidiaries and affiliates (collectively, "**Cephalon**") work together to manufacture, promote, distribute and sell both brand name and generic versions of the following opioids in the United States, Cabell County, and Plaintiff's Community:

Actiq/Fentanylcitrate/ScheduleII
Fentora/Fentanyl buccal/ScheduleII

71. From 2000 forward, Cephalon has made thousands of payments to physicians

nationwide, including in West Virginia, many of whom were not oncologists and did not treat cancer pain, ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services but in fact to deceptively promote and maximize the use of opioids.

72. Defendant **MALLINCKRODT PLC** is an Irish public limited company with its headquarters in Staines-Upon-Thames, Surrey, United Kingdom. Mallinckrodt PLC was incorporated in January 2013 for the purpose of holding the pharmaceuticals business of Covidien plc, which was fully transferred to Mallinckrodt plc in June of that year. Mallinckrodt plc also operates under the registered business name Mallinckrodt Pharmaceuticals, with its U.S. headquarters in Hazelwood, Missouri.

73. Defendant **MALLINCKRODT LLC** is a Delaware corporation with its headquarters in Hazelwood, Missouri.

74. Defendant **SPECGX LLC** is a Delaware limited liability company with its headquarters in Clayton, Missouri and is a wholly owned subsidiary of Mallinckrodt plc.

75. Mallinckrodt plc, Mallinckrodt LLC, and SpecGx LLC and their DEA registrant subsidiaries and affiliates (together, "**Mallinckrodt**") manufacture, market, sell and distribute pharmaceutical drugs throughout the United States. Mallinckrodt is the largest U.S. supplier of opioid pain medications and among the top ten generic pharmaceutical manufacturers in the United States, based on prescriptions.

76. Mallinckrodt manufactures and markets two branded opioids: Exalgo, which is extended-release hydromorphone, sold in 8, 12, 16, and 32 mg dosage strengths, and Roxicodone, which is oxycodone, sold in 15 and 30 mg dosage strengths. In 2009,

Mallinckrodt Inc., a subsidiary of Covidien plc, acquired the U.S. rights to Exalgo. The FDA approved Exalgo for treatment of chronic pain in 2012. Mallinckrodt further expanded its branded opioid portfolio in 2012 by purchasing Roxicodone from Xanodyne Pharmaceuticals. In addition, Mallinckrodt developed Xartemis XR, an extended-release combination of oxycodone and acetaminophen, which the FDA approved in March 2014, and which Mallinckrodt has since discontinued. Mallinckrodt promoted its branded opioid products with its own direct sales force.

77. While it has sought to develop its branded opioid products, Mallinckrodt has long been a leading manufacturer of generic opioids. Mallinckrodt estimated that in 2015 it received approximately 25% of the U.S. Drug Enforcement Administration's ("DEA") entire annual quota for controlled substances that it manufactures. Mallinckrodt also estimated, based on IMS Health data for the same period, that its generics claimed an approximately 23% market share of DEA Schedules II and III opioid and oral solid dose medications.

78. Mallinckrodt operates a vertically integrated business in the United States:

1) importing raw opioid materials and selling opioid API to other opioid manufacturers,
2) manufacturing generic opioid products, primarily at its facility in Hobart, New York, and
3) marketing and selling its products to drug distributors, specialty pharmaceutical distributors, retail pharmacy chains, pharmaceutical benefit managers that have mail-order pharmacies, and hospital buying groups.

79. Among the drugs Mallinckrodt manufactures or has manufactured are the following:

Product Name	Chemical Name	Schedule
Exalgo	Hydromorphone hydrochloride, extended release	Schedule II
Roxicodone	Oxycodone hydrochloride	Schedule II

Xartemis XR	Oxycodone hydrochloride and acetaminophen	Schedule II
Methadose	Methadone hydrochloride	Schedule II
Generic	Morphine sulfate, extended release	Schedule II
Generic	Morphine sulfate oral solution	Schedule II
Generic	Fentanyl transdermal system	Schedule II
Generic	Oral transmucosal fentanyl citrate	Schedule II
Generic	Oxycodone and acetaminophen	Schedule II
Generic	Hydrocodone bitartrate and acetaminophen	Schedule II
Generic	Hydromorphone hydrochloride	Schedule II
Generic	Hydromorphone hydrochloride, extended release	Schedule II
Generic	Naltrexone hydrochloride	unscheduled
Generic	Oxymorphone hydrochloride	Schedule II
Generic	Methadone hydrochloride	Schedule II
Generic	Oxycodone hydrochloride	Schedule II
Generic	Buprenorphine and naloxone	Schedule III

80. Mallinckrodt made thousands of payments to physicians nationwide ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, but in fact to deceptively promote and maximize the use of opioids.

81. Defendant **KVK-TECH, INC**. is a privately held Pennsylvania corporation with its principal place of business in Pennsylvania. KVK-Tech, Inc.is a manufacturer of generic prescription opioids, including many Schedule II controlled substances such as Oxycodone and Hydrocodone.

82. KVK-Tech, Inc. has engaged in the manufacture, promotion, distribution, and sale of the generic prescription opioid drugs sold throughout the country, including into West Virginia and Cabell County.

83. Defendant **AMNEAL Pharmaceuticals LLC** is a Delaware limited liability company with its principal place of business in Bridgewater, New Jersey. Impax laboratories, LLC, formerly known as Impax Laboratories, Inc., is a Delaware limited liability company with its principal place of business in Bridgewater, New Jersey. Upon information and belief, in May 2018, Impax laboratories, Inc. merged with and into Amneal pharmaceuticals LLC to form Defendant, Amneal Pharmaceuticals, Inc., a Delaware Corporation with its principal place of business in Bridgewater, New Jersey. Defendant Amneal Pharmaceuticals of New York LLC is a Delaware limited liability company with its principal place of business in Hauppauge, New York. Amneal Pharmaceuticals, Inc., Amneal Pharmaceuticals LLC, Amneal Pharmaceuticals of New York LLC, and Impax Laboratories, LLC are collectively referred to as "Amneal." Amneal manufactures, promotes, distributes and/or sells opioids nationally and in Cabell County and the City of Huntington.

II. JURISDICTION AND VENUE

This Court personal jurisdiction over each defendant as they conduct business in the State of Tennessee where this action was originally filed, purposefully direct or directed their actions toward the State of Tennessee, some or all consented to be sued in the State of Tennessee by registering an agent for service of process, because they consensually submitted to the jurisdiction of the State Tennessee when obtaining a manufacturer or distributor license, and because they have the requisite minimum contacts with the State of Tennessee necessary to constitutionally permit the Court to exercise jurisdiction.

This Court also has personal jurisdiction over all of the defendants under 18 U.S.C.§ 1965(b). This Court may exercise nation-wide jurisdiction over the named Defendants

where the "ends of justice" require national service and Plaintiff demonstrates national contacts. Here, the interests of justice require that Plaintiff be allowed to bring the members of the nationwide scheme before this Court.

This Court also has jurisdiction over the instant matter pursuant to 28 U.S.C.§ 1332(d) and the Class Action Fairness Act of 2005 ("CAFA"), 28 U.S.C. §§ 1711, *et seq.*, which vests original jurisdiction in the district courts of the United States for any multi-state class action where the aggregate amount in controversy exceeds $5 million and where the citizenship of any member of the class of plaintiffs is different from that of any defendant. The $5 million amount-in-controversy and diverse citizenship requirements of CAFA are satisfied in this case.

III. RELEVANT MARKETS

The relevant market in this case is the market for opioid medication, specifically directed to the thirty-one states listed herein.

IV. FRAUDULENT CONCEALMENT

The Plaintiff's claims are further subject to equitable tolling, stemming from Defendants' knowingly and fraudulently concealing the facts alleged herein. As alleged herein, Defendants knew of the wrongful acts set forth above, and had material information pertinent to their discover, and concealed them from the Plaintiff and Plaintiff's community. The Plaintiff did not know, or could not have known through the exercise of reasonable diligence, of its cause of action, as a result of Defendants' conduct.

V. FACTS COMMON TO ALL CLASS MEMBERS

This drug crisis began with a lie to create a market for opioid drugs. It started with a decision

by Purdue and the Sackler Defendants (collectively, "Purdue Entities"), to promote opioids deceptively and illegally in order to create a market for opioid drugs and significantly increase sales and costs to consumers, thereby generating billions of dollars in revenue for Purdue's private owners, the Sackler family.

Purdue's scheme was quickly joined by other manufacturers, including Endo Health Solutions Inc.; Endo Pharmaceuticals, Inc.; Par Pharmaceutical, Inc.; Par Pharmaceutical Companies, Inc. f/k/a Par Pharmaceutical Holdings, Inc.; Janssen Pharmaceuticals, Inc.; Ortho- McNeil-Janssen Pharmaceuticals, Inc. n/k/a Janssen Pharmaceuticals, Inc.; Janssen Pharmaceutica, Inc. n/k/a Janssen Pharmaceuticals, Inc.; Johnson & Johnson; Noramco, Inc.; Teva Pharmaceutical Industries, Ltd.; Teva Pharmaceuticals USA, Inc.; Cephalon, Inc.; Mallinckrodt PLC; Mallinckrodt LLC; SpecGx LLC, Amneal, and KVK Tech (collectively the "Defendants").

Defendants manufacture, market, sell, and distribute branded and/or generic prescription opioid pain medications. Some of the relevant brand-name drugs include OxyContin, Butrans, Hysingla ER, Actiq, Fentora, Opana/Opana ER, Percodan, Percocet, Zydone, Nucynta/Nucynta ER, Duragesic, Exalgo, and Xartemis XR. The Defendants used misrepresentations regarding the risks and benefits of opioids to enable the widespread prescribing of opioids for common, chronic pain conditions like low back pain, arthritis, and headaches.

Prescription opioids are narcotics. They are derived from and possess properties similar to opium and heroin, and they are regulated as controlled substances. While opioids can dampen the perception of pain, they also can create an addictive, euphoric high. At higher doses, they can slow the user's breathing, causing potentially fatal respiratory depression. Most patients receiving more than a few weeks of opioid therapy will experience withdrawal symptoms if opioid use is delayed or discontinued —including severe anxiety, nausea, headaches, tremors,

delirium, and pain—which are often prolonged. When using opioids continuously, patients grow tolerant to their analgesic effects (i.e. to relief of pain)—requiring progressively higher doses and increasing the risks of withdrawal, addiction, and overdose.

Because the medical community recognized these dangers, they originally used opioids cautiously and sparingly, typically only for short-term acute pain—where brief use limited the need for escalating doses and the risk of addiction—or for palliative (end-of-life) care. Consequently, the market for prescription opioids was sharply constrained.

As Purdue developed OxyContin in the mid-1990s, it knew that to expand its market and profits, it needed to change the perception of opioids to permit and encourage the use of opioids long-term for widespread chronic conditions like back pain, migraines, and arthritis. Purdue, joined by the other Defendants began to promote opioids generally, and their own opioids in particular, as safe, effective, and appropriate for even long-term use for routine pain conditions. As part of this strategy, Defendants misrepresented the risk of addiction for pain patients as modest, manageable, and outweighed by the benefits of opioid use.

The Defendants' scheme was resoundingly successful. Opioid therapy—the prescribing of opioids long-term to treat chronic pain—has become a commonplace, and often first-line, treatment. Defendants' deceptive marketing caused prescribing not only of their opioids, but of opioids as a class, to skyrocket. According to the CDC opioid prescriptions, as measured by number of prescriptions and morphine milligram equivalent ("MME") per person, tripled from 1999 to 2015. In 2015, on an average day, more than 650,000 opioid prescriptions were dispensed in the U.S. While previously a small minority of opioid sales, today between 80% and 90% of opioids (measured by weight) used are for chronic pain.

Thus, rather than compassionately helping patients, this explosion in opioid use— and

Defendants' profits—has come at the expense of chronic pain patients. As many as 1 in 4 patients who receive prescription opioids long-term for chronic pain in primary care settings struggles with addiction. Further, according to the CDC, one out of every 550 patients started on opioid therapy die of opioid-related causes a median of 2.6 years after their first opioid prescription. That number increases to 1 in 32 for patients receiving 200 MMEs per day. As the then CDC director concluded: "We know of no other medication routinely used for a nonfatal condition that kills patients so frequently."

Studies have linked the increased marketing of opioids to abuse, addiction and death. "Areas in this country hardest hit by the prescription opioid crisis were the same areas targeted by drug companies marketing opioids," said Scott Hadland, a pediatrician and researcher at the Grayken Center and also the lead author of a study linking marketing spends to opioids deaths.

Once the Defendants, employing the help of Distributors, created a mass market for prescription opioids, McKesson Corporation, AmerisourceBergen Drug Corporation, Cardinal Health, Inc., H.D. Smith Wholesale Drug Co., CVS, Rite Aid, Walgreens, Kroger, and Wal-Mart, Inc. (together "Distributor Defendants"), along with Defendants, flooded it. Defendants repeatedly shipped suspicious orders of opioids – often in quantities that they knew or should have known exceed any legitimate market for opioids, even the wider market for chronic pain, and ignored red flags of suspicious orders of these drugs in the Plaintiffs' Communities, thereby exacerbating the oversupply of such drugs and fueling an illegal secondary market.

A. **Opioids and Their Effect**

The medicinal properties of opioids have been recognized for millennia—as well as their potential for abuse and addiction. The opium poppy contains various opium alkaloids, three of which are used in the pharmaceutical industry today: morphine, codeine, and thebaine. Early

use of opium in Western medicine was with a tincture of opium and alcohol called laudanum, which contains all of the opium alkaloids and is still available by prescription today. Chemists first isolated the morphine and codeine alkaloids in the early 1800s.

In 1827, the pharmaceutical company Merck began large-scale production and commercial marketing of morphine. During the American Civil War, field medics commonly used morphine, laudanum, and opium pills to treat the wounded, and many veterans were left with morphine addictions. By 1900, an estimated 300,000 people were addicted to opioids in the United States, and many doctors prescribed opioids solely to prevent their patients from suffering withdrawal symptoms. The nation's first Opium Commissioner, Hamilton Wright, remarked in 1911, "The habit has this nation in its grip to an astonishing extent. Our prisons and our hospitals are full of victims of it, it has robbed ten thousand businessmen of moral sense and made them beasts who prey upon their fellows . . . it has become one of the most fertile causes of unhappiness and sin in the United States."

Pharmaceutical companies tried to develop substitutes for opium and morphine that would provide the same analgesic effects without the addictive properties. In 1898, Bayer Pharmaceutical Company began marketing diacetylmorphine (obtained from acetylation of morphine) under the trade name "Heroin." Bayer advertised heroin as a non-addictive cough and cold remedy suitable for children, but as its addictive nature became clear, heroin distribution in the U.S. was limited to prescription only in 1914 and then banned altogether a decade later.

Although heroin and opium became classified as illicit drugs, there is little difference between them and prescription opioids. Prescription opioids are synthesized from the same plant as heroin, have similar molecular structures, and bind to the same receptors in the human brain.

Due to concerns about their addictive properties, prescription opioids have usually been regulated at the federal level as Schedule II controlled substances by the U.S. Drug Enforcement Administration ("DEA") since 1970.

Throughout the twentieth century, pharmaceutical companies continued to develop prescription opioids like Percodan, Percocet, and Vicodin, but these opioids were generally produced in combination with other drugs, with relatively low opioid content.

In contrast, OxyContin, the product whose launch in 1996 ushered in the modern opioid epidemic, is pure oxycodone. Purdue initially made it available in the following strengths: 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg, 80 mg, and 160 mg. The weakest OxyContin delivers as much narcotic as the strongest Percocet, and some OxyContin tablets delivered sixteen times that.

Medical professionals describe the strength of various opioids in terms of morphine milligram equivalents ("MME"). According to the CDC, doses at or above 50 MME/day double the risk of overdose compared to 20 MME/day, and one study found that patients who died of opioid overdose were prescribed an average of 98 MME/day.

Different opioids provide varying levels of MMEs. For example, just 33 mg of oxycodone provides 50 MME. Thus, at OxyContin's twice daily dosing; the 50 MME/day threshold is nearly reached by a prescription of 15 mg twice daily. One 160 mg tablet of OxyContin, which Purdue took off the market in 2001, delivered 240 MME.

The wide variation in the MME strength of prescription opioids renders misleading any effort to capture "market share" by the number of pills or prescriptions attributed to Purdue or other manufacturers. Purdue, in particular, focuses its business on branded, highly potent pills,

causing it to be responsible for a significant percent of the total amount of MME in circulation, even though it currently claims to have a small percent of the market share in terms of pills or prescriptions.

Fentanyl is a synthetic opioid that is 100 times stronger than morphine and 50 times stronger than heroin. First developed in 1959, fentanyl is showing up more and more often in the market for opioids created by Defendants' promotion, with particularly lethal consequences.

The effects of opioids vary by duration. Long-acting opioids, such as Purdue's OxyContin and MS Contin, Janssen's Nucynta ER and Duragesic, Endo's Opana ER, and Actavis's Kadian, are designed to be taken once or twice daily and are purported to provide continuous opioid therapy for, in general, 12 hours. Short-acting opioids, such as Cephalon's Actiq and Fentora, are designed to be taken in addition to long-acting opioids to address "episodic pain" (also referred to as "breakthrough pain") and provide fast-acting, supplemental opioid therapy lasting approximately 4 to 6 hours. Still other short-term opioids, are designed to be taken in addition to long-acting opioids to specifically address breakthrough cancer pain, excruciating pain suffered by some patients with end-stage cancer. The Defendants promoted the idea that pain should be treated by taking long-acting opioids continuously and supplementing them by also taking short-acting, rapid-onset opioids for episodic or "breakthrough" pain.

Patients develop tolerance to the analgesic effect of opioids relatively quickly. As tolerance increases, a patient typically requires progressively higher doses in order to obtain the same perceived level of pain reduction. The same is true of the euphoric effects of opioids—the "high." However, opioids depress respiration, and at very high doses can and often do arrest respiration altogether. At higher doses, the effects of withdrawal are more severe. Long-term opioid use can also cause hyperalgesia, a heightened sensitivity to pain.

Discontinuing opioids after more than just a few weeks of therapy will cause most patients to experience withdrawal symptoms. These withdrawal symptoms include: severe anxiety, nausea, vomiting, headaches, agitation, insomnia, tremors, hallucinations, delirium, pain, and other serious symptoms, which may persist for months after a complete withdrawal from opioids, depending on how long the opioids were used.

B. The Resurgence of Opioid Use in the U.S.- The Sackler Family Integrated Advertising and Medicine

Given the history of opioid abuse in the U.S. and the medical profession's resulting wariness, the commercial success of the Defendants' prescription opioids would not have been possible without a fundamental shift in prescribers' perception of the risks and benefits of long-term opioid use.

As it turned out, Purdue Pharma was uniquely positioned to execute just such a maneuver, thanks to the legacy of a man named Arthur Sackler. The Sackler family is the sole owner of Purdue and one of the wealthiest families in America, with a net worth of $13 billion as of 2016. The company's profits go to Sackler family trusts and entities. Yet the Sacklers have avoided publicly associating themselves with Purdue, letting others serve as the spokespeople for the company.

The Sackler brothers—Arthur, Mortimer, and Raymond—purchased a small patent-medicine company called the Purdue Frederick Company in 1952. It was Arthur Sackler who created the pharmaceutical advertising industry, as we know it, laying the groundwork for the OxyContin promotion that would make the Sacklers billionaires.

Arthur Sackler was both a psychiatrist and a marketing executive. He pioneered both print

advertising in medical journals and promotion through physician "education" in the form of seminars and continuing medical education courses. He also understood the persuasive power of recommendations from fellow physicians, and did not hesitate to manipulate information when necessary. For example, one promotional brochure produced by his firm for Pfizer showed business cards of physicians from various cities as if they were testimonials for the drug, but when a journalist tried to contact these doctors, he discovered that they did not exist.

It was Arthur Sackler who, in the 1960s, made Valium into the first $100-million drug, so popular it became known as "Mother's Little Helper." When Arthur's client, Roche, developed Valium, it already had a similar drug, Librium, another benzodiazepine, on the market for treatment of anxiety. So Arthur invented a condition he called "psychic tension"—essentially stress—and pitched Valium as the solution. The campaign, for which Arthur was compensated based on volume of pills sold, was a remarkable success.

Arthur Sackler created not only the advertising for his clients but also the vehicle to bring their advertisements to doctors—a biweekly newspaper called the Medical Tribune, which was distributed for free to doctors nationwide. Arthur also conceived a company now called IMS Health Holdings Inc., which monitors prescribing practices of every doctor in the U.S. and sells this valuable data to pharmaceutical companies like Defendants, who utilize it to target and tailor their sales pitches to individual physicians.

C. **Purdue and the Development of OxyContin**

After the Sackler brothers acquired the Purdue Frederick Company in 1952, Purdue sold products ranging from earwax remover to antiseptic, and it became a profitable business. As an advertising executive, Arthur Sackler was not involved, on paper at least, in running Purdue. Raymond Sackler became Purdue's head executive, while Mortimer Sackler ran Purdue's UK

affiliate.

In the 1980s, Purdue, through its UK affiliate, acquired a Scottish drug producer that had developed a sustained-release technology suitable for morphine. Purdue marketed this extended-release morphine as MS Contin, and it quickly became Purdue's bestseller. As the patent expiration for MS Contin loomed, Purdue searched for a drug to replace it. Around that time, Raymond's oldest son, Richard Sackler, who was also a trained physician, became more involved in the management of the company. Richard had grand ambitions for the company; according to a long-time Purdue sales representative, "Richard really wanted Purdue to be big—I mean really big." Richard believed Purdue should develop another use for its "Contin" timed-release system.

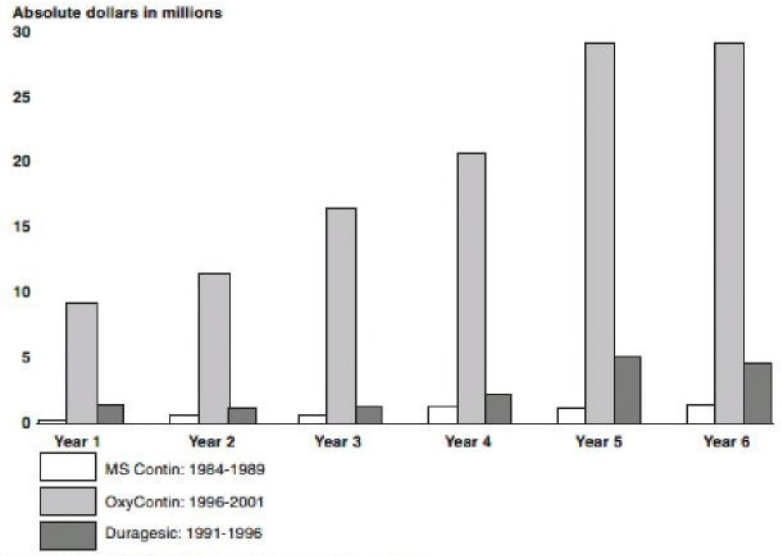
In 1990, Purdue's vice president of clinical research, Robert Kaiko, sent a memo to Richard and other executives recommending that the company work on a pill containing oxycodone. At the time, oxycodone was perceived as less potent than morphine, largely because it was most commonly prescribed as Percocet, a relatively weak oxycodone-acetaminophen combination pill. MS Contin was not only approaching patent expiration but had always been limited by the stigma associated with morphine. Oxycodone did not have that problem, and what's more, it was sometimes mistakenly called "oxycodeine," which also contributed to the perception of relatively lower potency, because codeine is weaker than morphine. Purdue acknowledged using this to its advantage when it later pled guilty to criminal charges of "misbranding" in 2007, admitting that it was "well aware of the incorrect view held by many physicians that oxycodone was weaker than morphine" and "did not want to do anything 'to make physicians think that oxycodone was stronger or equal to morphine' or to 'take any steps . . . that would affect the unique position that OxyContin'" held among physicians.

For Purdue and OxyContin to be "*really* big," Purdue needed to both distance its new product from the traditional view of narcotic addiction risk, and broaden the drug's uses beyond cancer pain and hospice care. A marketing memo sent to Purdue's top sales executives in March 1995 recommended that if Purdue could show that the risk of abuse was lower with OxyContin than with traditional immediate-release narcotics, sales would increase. As discussed below, Purdue did not find or generate any such evidence, but this did not stop Purdue from making that claim regardless.

Armed with this and other misrepresentations about the risks and benefits of its new drug, Purdue was able to open an enormous untapped market: patients with non-end-of-life, non- acute, everyday aches and pains. As Dr. David Haddox, a Senior Medical Director at Purdue, declared on the Early Show, a CBS morning talk program, "There are 50 million patients in this country who have chronic pain that's not being managed appropriately every single day. OxyContin is one of the choices that doctors have available to them to treat that."

In pursuit of these 50 million potential customers, Purdue poured resources into OxyContin's sales force and advertising, particularly to a far broader audience of primary care physicians who treated patients with chronic pain complaints. The graph below shows how promotional spending in the first six years following OxyContin's launch dwarfed Purdue's spending on MS Contin or Defendant Janssen's spending on Duragesic.

Figure 1: Promotional Spending for Three Opioid Analgesics in First 6 Years of Sales



Source: DEA and IMS Health, Integrated Promotional Service Audit.

Note: Dollars are 2002 adjusted.

Prior to Purdue's launch of OxyContin, no drug company had ever promoted such a pure, high-strength Schedule II narcotic to so wide an audience of general practitioners.

In the two decades following OxyContin's launch, Purdue continued to devote substantial resources to its promotional efforts.

Purdue has generated estimated sales of more than $35 billion from opioids since 1996, raking in more than $3 billion in 2015 alone. Remarkably, its opioid sales continued to climb even after a period of media attention and government inquiries regarding OxyContin abuse in the early 2000s and a criminal investigation culminating in guilty pleas in 2007. Purdue proved itself skilled at evading full responsibility and continuing to sell through the controversy. The company's annual opioid sales of $3 billion in 2015 represent a four-fold increase from its 2006 sales of $800 million.

D. **Other Defendants Join Purdue's Scheme**

Purdue created a market for the use of opioids for a range of common aches and pains by misrepresenting the risks and benefits of its opioids, but it was far from alone. The other Defendants—already manufacturers of prescription opioids—positioned themselvesto join Purdue. The other defendants both branded and generic opioids to compete with OxyContin, while, together with Purdue and each other, misrepresenting the safety and efficacy of their products. These misrepresentations are described in greater detail below.

Endo, which already sold Percocet and Percodan, was the first to submit an application for a generic extended-release oxycodone to compete with OxyContin. At the same time, Endo sought FDA approval for another potent opioid, immediate-release and extended- release oxymorphone, branded as Opana and Opana ER. Oxymorphone, like OxyContin's active ingredient oxycodone, is not a new drug; it was first synthesized in Germany in 1914 and sold in the U.S. by Endo beginning in 1959 under the trade name Numorphan. But Numorphan tablets proved highly susceptible to abuse. Called "blues" after the light blue color of the 10 mg pills, Numorphan provoked, according to some users, a more euphoric high than heroin. As the National Institute on Drug Abuse observed in its 1974 report, "Drugs and Addict Lifestyle," Numorphan was extremely popular among addicts for its quick and sustained effect. Endo withdrew oral Numorphan from the market in 1979.

Two decades later, however, as communities around the U.S. were first sounding the alarm about prescription opioids and Purdue executives were being called to testify before Congress about the risks of OxyContin, Endo essentially reached back into its inventory, dusted off a product it had previously shelved after widespread abuse, and pushed it into the marketplace with a new trade name, Opana.

The clinical trials submitted with Endo's first application for approval of Opana were

insufficient to demonstrate efficacy, and some subjects in the trials overdosed and had to be revived with naloxone. Endo then submitted new "enriched enrollment" clinical trials, in which trial subjects who do not respond to the drug are excluded from the trial, and obtained approval. Endo began marketing Opana and Opana ER in 2006.

Like Numorphan, Opana ER was highly susceptible to abuse. On June 8, 2017, the FDA sought removal of Opana ER. In its press release, the FDA indicated that "[t]his is the first time the agency has taken steps to remove a currently marketed opioid pain medication from sale due to the public health consequences of abuse." On July 6, 2017, Endo agreed to withdraw Opana ER from the market. Janssen, which already marketed the Duragesic (fentanyl) patch for severe pain, also joined Purdue in pursuit of the broader chronic pain market. It sought to expand the use of Duragesic through, for example, advertisements proclaiming, "It's not just for end stage cancer anymore!" This claim earned Janssen a warning letter from the FDA, for representing that Duragesic was "more useful in a broader range of conditions or patients than has been demonstrated by substantial evidence."

Janssen also developed a new opioid compound called tapentadol in 2009, marketed as Nucynta for the treatment of moderate to severe pain. Janssen launched the extended- release version, Nucynta ER, for treatment of chronic pain in 2011.

Not only did Janssen manufacture its own branded drugs, but also, its subsidiaries Tasmanian Alkaloids and Noramco were responsible for processing the active pharmaceutical ingredients ("API") for other opioid manufacturers. As a result, Janssen profited from the growth of both unbranded and branded opioids and was driven to develop the market as much as possible.

Janssen had a global Active Pharmaceutical Ingredients (API) manufacturing network for opiate analgesics and antagonists. Noramco and Tasmanian Alkaloids were the primary

suppliers of the active pharmaceutical ingredients provided to a number of opioid manufacturers. As stated above, eighty percent of Noramco's sales were with all 7 of the top U.S. generic companies. Companies Noramco supplied included Teva, Endo, Purdue, Rhodes, Mallinckrodt, Actavis, Amneal and KVK. Noramco's product portfolio includes Oxycodone (OxyContin, Percocet, Roxicodone), Hydrocodone (Vicodin, Lortab), Morphine (MS Contin, Embeda).

In 1994, Janssen's subsidiary, Tasmanian Alkaloids, established a research project "in order to develop a high thebaine poppy to meet the anticipated demand." This project resulted in the development of the "Norman" poppy. It's development "coincided with the release of a slow release formulation of oxycodone in the USA." The company reported:

The new formulation was very successful, and there was greatly increased demand for the thebaine raw material used for its manufacture.

This new poppy variety is a major turning point in alkaloid production.

The high alkaloid content of the Tasmanian crop is our most important competitive advantage.

Patented, high thebaine poppy was a transformational technology that enabled the growth of oxycodone.

API volume growth linked to generics of branded drugs, new delivery systems & abuse prevention claims.

Noramco steadily gained in the U.S. market share reporting in 2014 alone that U.S. Sales of $94MM for Oxycodone and $52MM for Hydrocodone. In five years, from 2006 – 2011 their API volume growth doubled and continued climbing for the need for new capacity in 2015. Janssen's fully integrated supply chain provided security for continued growth.

Janssen fueled the opioid epidemic by providing a more potent poppy that could provide greater supply and/or profits. But, because of Noramco and Tasmanian Alkaloids, Janssen had an incentive to fraudulently market opioids with other Defendants as Janssen profited not only from its own opioid products, but from the sale of its API to other manufacturers.

Ironically, Janssen also profited from the rising addictions and abuse of opioids by supplying API for use in Naloxone for overdose and abuse, and in Naltrexone and Buprenorphine for opioid addiction.

By adding additional opioids or expanding the use of their existing opioid products, the other Defendants took advantage of the market created by Purdue's aggressive promotion of OxyContin and reaped enormous profits. For example, Opana ER alone generated more than $1 billion in revenue for Endo in 2010 and again in 2013. Janssen also passed the $1 billion mark in sales of Duragesic in 2009.

E. **The Defendants' Multi-Pronged Scheme to Change Prescriber Habits and Public Perception and Increase Demand for Opioids**

Until the mid-1990s, opioids were widely thought to be too addictive for use for chronic pain conditions, which would require long-term use of the drugs at increasingly high doses. For these conditions, the risks of addiction and other side effects outweighed any benefit from the drugs. Over the last two decades, Defendants turned that consensus on its head by designing and implementing a sophisticated and deceptive market strategy that, among other things, falsely denied the risk of addiction and overstated the benefits of using opioids long-term.

Lacking legitimate scientific research to support their claims, Defendants turned to the marketing techniques first pioneered by Arthur Sackler to create a series of misperceptions in

the medical community and ultimately reverse the long-settled understanding of the relative risks and benefits of opioids.

Through marketing that was as pervasive as it was deceptive, Defendants convinced health care providers both that the risks of long-term opioid use were overblown and that the benefits, in reduced pain and improved function and quality of life, were proven. Purdue, for example, promoted the concept that pain was undertreated, that opioids could not be abused, that the rate of addiction to opioids was less than 1%, that "old views" of opioid addiction were untrue, and that "appropriate patients" would not become addicted.

The result was that by the mid-2000s, the medical community had abandoned its prior caution, and opioids were entrenched as an appropriate—and often the first—treatment for chronic pain conditions. Defendants not only marketed opioids for chronic pain conditions, but also targeted primary care physicians (along with nurse practitioners and physician assistants), who were most likely to see patients with chronic pain conditions and least likely to have the training and experience to evaluate Defendants' marketing claims.

Defendants' deceptive marketing created a cadre of doctors who looked for pain and treated it with opioids, which created an even broader cohort of patients who expected and received opioids. This laid the groundwork for today's epidemic of opioid addiction, injury, and death.

The Defendants promoted, and profited from, their misrepresentations about the risks and benefits of opioids for chronic pain even though they knew that their marketing was false and misleading. The history of opioids, as well as research and clinical experience over the last 20 years, established that opioids were highly addictive and responsible for a long list of very serious adverse outcomes. The FDA and other regulators warned Defendants of these risks. The Defendants had access to scientific studies, detailed prescription data, and reports of adverse

events, including reports of addiction, hospitalization, and deaths—all of which made clear the harms from long-term opioid use and that patients are suffering from addiction, overdoses, and death in alarming numbers. More recently, the FDA and CDC issued pronouncements based on existing medical evidence that conclusively expose the known falsity of these Defendants' misrepresentations.

The scheme to increase opioid prescriptions centered around nine categories of misrepresentations, which are discussed in detail below. The Defendants disseminated these misrepresentations through various channels, including through advertising, sales representatives, purportedly independent organizations these defendants funded and controlled, "Front Groups," so-called industry "Key Opinion Leaders," and Continuing Medical Education ("CME") programs discussed subsequently below.

F. The Defendants Promoted Multiple Falsehoods About Opioids

Defendants spent hundreds of millions of dollars on promotional activities and materials, including advertising, and websites that falsely denied or trivialized the risk of addiction and overstated the benefits of opioids. They also relied upon unsupported and misleading information derived from seminars, treatment guidelines, and other publications and programs by patient advocacy groups, professional associations, and physicians that seemed independent and therefore credible, but were actually funded and controlled by Defendants.

For example, Purdue recruited and paid respected health care professionals as "speakers" who presented Purdue-approved programs to other prescribers at lunch and dinner events. From 1996 to 2001, Purdue held more than 40 national conferences and more than 5,000 physicians, pharmacist, and nurses attended these speaker conferences. In addition to speaker programs, Purdue targeted doctors with "educational" programing and funded more than 20,000 pain-

related educational programs through direct sponsorship or financial grants by July 2002.

Defendants also used "key opinion leaders" ("KOLs")—experts in the field who were especially influential because of their reputations and seeming objectivity—to deliver paid talks and continuing medical education programs (or "CMEs") that provided information about treating pain and the risks, benefits, and use of opioids. These KOLs received substantial funding and research grants from the Defendants, and the CMEs were often sponsored by Defendants—giving them considerable influence over the messenger, the message, and the distribution of the program. Only doctors supportive of the use and safety of opioids for chronic pain received these funding and speaking opportunities, which were not only lucrative, but also helped doctors build their reputations and bodies of work. One notable KOL, Dr. Russell Portenoy, subsequently acknowledged that he gave lectures on opioids that reflected "misinformation" and were "clearly the wrong thing to do."

In addition to talks and CMEs, these KOLs served on the boards of patient advocacy groups and professional associations, such as the American Pain Foundation and the American Pain Society, which also took money directly from Defendants in an organized effort to exert greater influence because of their seeming independence. According to a report issued by the U.S. Senate Homeland Security & Governmental Affairs Committee, Ranking Member's Office, "many patient advocacy organizations and professional societies focusing on opioids policy have promoted messages and policies favorable to opioid use while receiving millions of dollars in payments from opioid manufacturers. Through criticism of government prescribing guidelines, minimization of opioid addiction risk, and other efforts, ostensibly neutral advocacy organizations have often supported industry interests at the expense of their own constituencies." These "front groups" for the opioid industry put out unbranded patient education materials and

treatment guidelines that supported the use of opioids for chronic pain, overstated their benefits, and understated their risks. In many instances, Defendants distributed these publications to prescribers, including, upon information and belief, prescribers in the City, or posted them on their websites.

These third-party, unbranded materials were not reviewed or approved by the FDA.

The FDA does not regulate all conduct engaged in by these Defendants. Marketing for chronic pain is not specifically approved. Medication labels do not address the use of opioids in treating specific conditions such as lower back pain, headaches, or fibromyalgia—three conditions for which opioids are not effective, but for which these Defendants marketed their drugs. Nor do the labels approve of the concept of "pseudoaddiction" or the technique of suggesting that abuse deterrent formulations are safer. In addition, though labels contain warnings about addiction, they do not quantify the severity of the risk. Defendants' asserted in branded and unbranded marketing that screening, abuse deterrent formulations, or urinalysis could adequately manage the risk of developing an addiction without evidence to support these claims.

- The Defendants' misrepresentations generally fall into the following nine categories:
- The risk of addiction from opioid therapy is low
- Signs of addictive behavior are "pseudoaddiction," requiring more opioids
- To the extent there is a risk of addiction, it can be easily identified and managed
- Opioid withdrawal can be avoided by tapering
- Long-term opioid use improves functioning

- Opioid doses can be increased without limit or greater risks
- Alternative forms of pain relief pose greater risks than opioids
- OxyContin provides twelve hours of pain relief
- New formulations of certain opioids successfully deter abuse

Each of these propositions was false. The Defendants knew this, but they nonetheless set out to convince physicians, patients, and the public at large of the truth of each of these propositions in order to expand the market for their opioids.

The categories of misrepresentations are offered to organize the numerous statements the Defendants made and to explain their role in the overall marketing effort, not as a checklist for assessing each Defendant's liability. While each Defendant deceptively promoted their opioids specifically, and, together with other Defendants, opioids generally, not every Defendant propagated (or needed to propagate) each misrepresentation. Each Defendant's conduct, and each misrepresentation, contributed to an overall narrative that aimed to—and did—mislead doctors, patients, and payors about the risk and benefits of opioids. While this Complaint endeavors to document examples of each Defendant's misrepresentations and the manner in which they were disseminated, they are just that—examples. The Complaint is not, especially prior to discovery, an exhaustive catalog of the nature and manner of each deceptive statement by each Defendant.

Upon information and belief, all of the messages described below were disseminated to prescribers and patients in Plaintiffs' communities.

Falsehood #1: The risk of addiction from chronic opioid therapy is low

To convince prescribers and patients that opioids are safe, Defendants deceptively represented

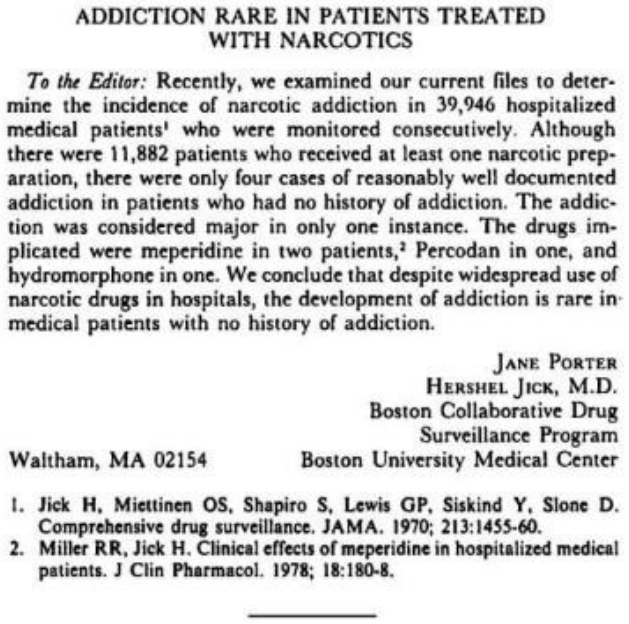
that the risk of abuse and addiction is modest and manageable and limited to illegitimate patients, not those with genuine pain. This created the dangerously misleading impressions that: (1) patients receiving opioid prescriptions for chronic pain would not become addicted, (2) patients at greatest risk of addiction could be identified, and (3) all other patients could safely be prescribed opioids.

Defendants undermined evidence that opioids are addictive by suggesting or stating that the risk of addiction is limited to high-risk patients. These Defendants also minimized the difficulty of withdrawal in their marketing material and promotional programs. For example, a 2011 non-credit educational program sponsored by Endo, entitled Persistent Pain in the Older Adult, claimed that withdrawal symptoms, which make it difficult for patients to stop using opioids, could be avoided by simply tapering a patient's opioid dose over ten days. However, this claim is at odds with the experience of patients addicted to opioids. Most patients who are dependent upon or addicted to opioids will experience withdrawal, characterized by intense physical and psychological effects, including anxiety, nausea, headaches, and delirium, among others. This painful and arduous struggle to terminate use can leave many patients unwilling or unable to give up opioids and heightens the risk of addiction.

Purdue's misrepresentations regarding addiction risk

When it launched OxyContin, Purdue knew it would need data to overcome decades of wariness regarding opioid use. It needed some sort of research to back up its messaging. But Purdue had not conducted any studies about abuse potential or addiction risk as part of its application for FDA approval for OxyContin. Purdue (and, later, the other Defendants) found this "research" in the form of a one-paragraph letter to the editor published in the *New England Journal of Medicine* (NEJM) in 1980.

This letter, by Dr. Hershel Jick and Jane Porter, declared the incidence of addiction "rare" for patients treated with opioids. They had analyzed a database of hospitalized patients who were given opioids in a controlled setting to ease suffering from acute pain. Porter and Jick considered a patient not addicted if there was no sign of addiction noted in patients' records.



ADDICTION RARE IN PATIENTS TREATED WITH NARCOTICS

To the Editor: Recently, we examined our current files to determine the incidence of narcotic addiction in 39,946 hospitalized medical patients[1] who were monitored consecutively. Although there were 11,882 patients who received at least one narcotic preparation, there were only four cases of reasonably well documented addiction in patients who had no history of addiction. The addiction was considered major in only one instance. The drugs implicated were meperidine in two patients,[2] Percodan in one, and hydromorphone in one. We conclude that despite widespread use of narcotic drugs in hospitals, the development of addiction is rare in medical patients with no history of addiction.

JANE PORTER
HERSHEL JICK, M.D.
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1. Jick H, Miettinen OS, Shapiro S, Lewis GP, Siskind Y, Slone D. Comprehensive drug surveillance. JAMA. 1970; 213:1455-60.
2. Miller RR, Jick H. Clinical effects of meperidine in hospitalized medical patients. J Clin Pharmacol. 1978; 18:180-8.

As Dr. Jick explained to a journalist years later, he submitted the statistics to NEJM as a letter because the data were not robust enough to be published as a study.

Purdue nonetheless began repeatedly citing this letter in promotional and educational materials as evidence of the low risk of addiction, while failing to disclose that its source was a letter to the editor, not a peer-reviewed paper. Citation of the letter, which was largely ignored for more than a decade, significantly increased after the introduction of OxyContin. While first Purdue and then other Defendants used it to assert that their opioids were not addictive, "that's not in any shape or form what we suggested in our letter," according to Dr. Jick.

Purdue specifically used the Porter and Jick letter in its 1998 promotional video, "I got my life back," in which Dr. Alan Spanos says, "In fact, the rate of addiction amongst pain patients who

are treated by doctors *is much less than 1%*." Purdue trained its sales representatives to tell prescribers that fewer than 1% of patients who took OxyContin became addicted. (In 1999, a Purdue-funded study of patients who used OxyContin for headaches found that the addiction rate was thirteen per cent.)"

Other Defendants relied on and disseminated the same distorted messaging. The enormous impact of Defendants' misleading amplification of this letter was well documented in another letter published in the NEJM on June 1, 2017, describing the way the one-paragraph 1980 letter had been irresponsibly cited and in some cases "grossly misrepresented." In particular, the authors of this letter explained:

[W]e found that a five-sentence letter published in the *Journal* in 1980 was heavily and uncritically cited as evidence that addiction was rare with long-term opioid therapy. We believe that this citation pattern contributed to the North American opioid crisis by helping to shape a narrative that allayed prescribers' concerns about the risk of addiction associated with long-term opioid therapy . . .

"It's difficult to overstate the role of this letter," said Dr. David Juurlink of the University of Toronto, who led the analysis. "It was the key bit of literature that helped the opiate manufacturers convince front-line doctors that addiction is not a concern."

Alongside its use of the Porter and Jick letter, Purdue also crafted its own materials and spread its deceptive message through numerous additional channels. In its 1996 press release announcing the release of OxyContin, for example, Purdue declared, "The fear of addiction is exaggerated."

At a hearing before the House of Representatives' Subcommittee on Oversight and

Investigations of the Committee on Energy and Commerce in August 2001, Purdue emphasized "legitimate" treatment, dismissing cases of overdose and death as something that would not befall "legitimate" patients: "Virtually all of these reports involve people who are abusing the medication, not patients with legitimate medical needs under the treatment of a healthcare professional."

Purdue spun this baseless "legitimate use" distinction out even further in a patient brochure about OxyContin, called "A Guide to Your New Pain Medicine and How to Become a Partner Against Pain." In response to the question "Aren't opioid pain medications like OxyContin Tablets 'addicting'?," Purdue claimed that there was no need to worry about addiction if taking opioids for legitimate, "medical" purposes:

Drug addiction means using a drug to get "high" rather than to relieve pain. You are taking opioid pain medication for medical purposes. The medical purposes are clear and the effects are beneficial, not harmful.

Sales representatives marketed OxyContin as a product "'to start with and to stay with.'" Sales representatives also received training in overcoming doctors' concerns about addiction with talking points they knew to be untrue about the drug's abuse potential. One of Purdue's early training memos compared doctor visits to "firing at a target," declaring that "[a]s you prepare to fire your 'message,' you need to know where to aim and what you want to hit!"

According to the memo, the target is physician resistance based on concern about addiction: "The physician wants pain relief for these patients without addicting them to an opioid."

Purdue, through its unbranded website *Partners Against Pain*, stated the following: "Current Myth: Opioid addiction (psychological dependence) is an important clinical problem in patients

with moderate to severe pain treated with opioids. Fact: Fears about psychological dependence are exaggerated when treating appropriate pain patients with opioids." "Addiction risk also appears to be low when opioids are dosed properly for chronic, noncancer pain."

Former sales representative Steven May, who worked for Purdue from 1999 to 2005, explained to a journalist how he and his coworkers were trained to overcome doctors' objections to prescribing opioids. The most common objection he heard about prescribing OxyContin was that "it's just too addictive." May and his coworkers were trained to "refocus" doctors on "legitimate" pain patients, and to represent that "legitimate" patients would not become addicted. In addition, they were trained to say that the 12-hour dosing made the extended-release opioids less "habit-forming" than painkillers than need to be taken every four hours.

According to interviews with prescribers and former Purdue sales representatives, Purdue has continued to distort or omit the risk of addiction while failing to correct its earlier misrepresentations, leaving many doctors with the false impression that pain patients will only rarely become addicted to opioids.

With regard to addiction, Purdue's label for OxyContin has not sufficiently disclosed the true risks to, and experiences of, its patients. Until 2014, the OxyContin label stated in a black-box warning that opioids have "abuse potential" and that the "risk of abuse is increased in patients with a personal or family history of substance abuse."

However, the FDA made clear to Purdue as early as 2001 that the disclosures in its OxyContin label were insufficient. Senior FDA officials met with Purdue on April 23, 2001, to "provide comments and suggestions on a Risk Management program for OxyContin. "Among other issues, the FDA noted that Purdue should add a black-box warning for overdose, abuse, and death to OxyContin's label. Purdue acknowledged that it was aware of abuse of OxyContin

orally (without tampering), as well as by snorting or injecting. It was not, the FDA explained, a matter of changing a few words in OxyContin's label; Dr. Cynthia McCormick, then director of the FDA division overseeing pain medication, declared that "'major overhaul is my message.' The prescribing of OxyContin is creeping into a whole population of people where it doesn't belong. Just rewriting the abuse and dependence section won't help much, that part of the insert is not a pivot point."

Another FDA participant asked that Purdue "refocus our promotional materials and make the risks of abuse and diversion more prominent." In short, the FDA advised Purdue "that the information put in the label back at the time of product approval did not adequately address the risks associated with this product and this needs to be corrected."

In 2001, Purdue revised the indication and warnings for OxyContin, but did not go nearly as far as the FDA recommended or the known risks of the product demanded. In the United States, Purdue ceased distributing the 160 mg tablet of OxyContin. While Purdue agreed to "consider" changes to its label, it also expressed a reluctance to make significant changes not required for other prescription opioids. Dr. McCormick noted that the issues discussed at the meeting were specific to OxyContin and that, while the Agency would talk with Purdue's competitors, "'we have a problem here and now with OxyContin.' In due time other manufacturers will be contacted but the first problem is this product."

In the end, Purdue narrowed the recommended use of OxyContin to situations when "a continuous, around-the-clock analgesic is needed for an extended period of time" and added a warning that "[t]aking broken, chewed, or crushed OxyContin tablets" could lead to a "potentially fatal dose." However, Purdue did not, until 2014, change the label as the FDA suggested, to indicate that OxyContin should not be the first therapy, or even the first opioid,

used, and did not disclose the incidence or risk of overdose and death even when OxyContin was not abused. Purdue announced the label changes in a letter to health care providers but did not, as the FDA suggested, issue "a Medguide for patients on the risks of overdose and the abuse of opioids as well as risks for use by others than those for whom it was prescribed" or undertake the recommended promotional effort to educate patients about the potentially fatal risks of OxyContin.

The FDA also informed Purdue what Purdue already knew, as noted above—that "there is a perception that oxycodone is safer than morphine." A representative from the FDA's Division of Drug Marketing, Advertising and Communications echoed this, calling for an "extensive educational effort to consumers and health care practitioners" to "correct a misconception that [OxyContin] is different than morphine." Upon information and belief, Purdue never undertook that effort.

Purdue also heavily promoted the Joint Commission on Accreditation of Healthcare Organization's Pain as a Fifth Vital Sign, which encouraged health care providers to ask about pain and, presumably, to treat it with opioids. Purdue obtained exclusive rights to distribute Pain as a Fifth Vital Sign, and made sure that this guide, intended initially for hospital patients, was widely disseminated. Front groups supported by Defendants, particularly the University of Wisconsin Pain and Policy Study Group (PPSG), proposed the concept of Pain as a Fifth Vital Sign, which the review committee of outside physicians charged with evaluating guidelines rejected precisely because of their concern that it would result in overuse of opioids and increased addiction and overdose. JACHO nonetheless adopted by guidelines, presumably at the behest of PPSG and its supporters.

Endo's misrepresentations regarding addiction risk

Endo also falsely represented that addiction is rare in patients who are prescribed opioids.

Until April 2012, Endo's website for Opana, *www.opana.com*, stated that "[m]ost healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted."

Upon information and belief, Endo improperly instructed its sales representatives to diminish and distort the risk of addiction associated with Opana ER. Endo's training materials for its sales representatives in 2011 also prompted sales representatives to answer "true" to the statement that addiction to opioids is not common.

One of the Front Groups with which Endo worked most closely was the American Pain Foundation ("APF"), described more fully below. Endo provided substantial assistance to, and exercised editorial control, over the deceptive and misleading messages that APF conveyed through its National Initiative on Pain Control ("NIPC")[106] and its website *Painknowledge.com*, which claimed that "[p]eople who take opioids as prescribed usually do not become addicted."

Another Endo website, *PainAction.com*, stated: "Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them."

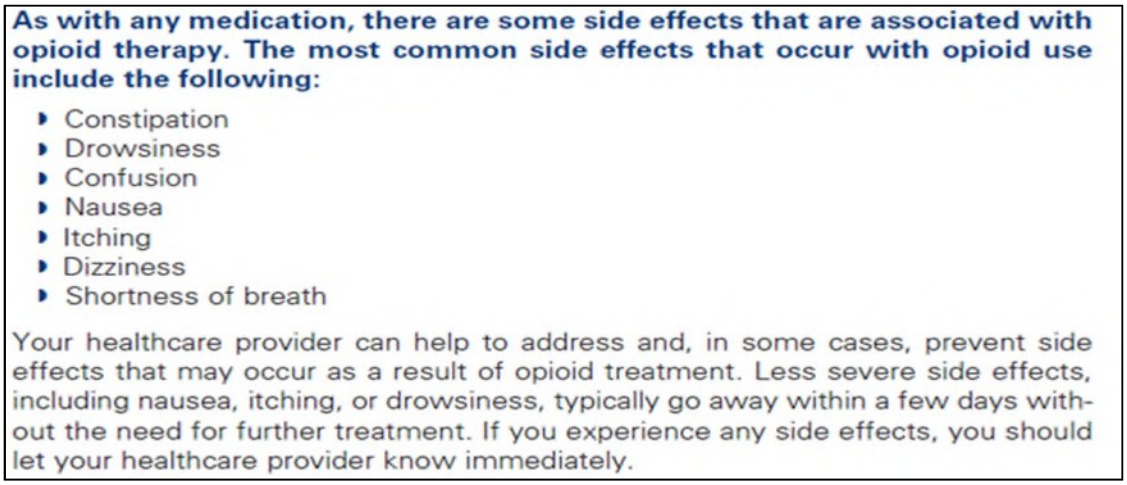
A brochure available on *Painknowledge.com* titled "*Pain: Opioid Facts*," Endo- sponsored NIPC stated that "people who have no history of drug abuse, including tobacco, and use their opioid medication as directed will probably not become addicted." In numerous patient education pamphlets, Endo repeated this deceptive message.

In a patient education pamphlet titled "*Understanding Your Pain: Taking Oral Opioid Analgesics*," Endo answers the hypothetical patient question—"What should I know about

opioids and addiction?"—by focusing on explaining what addiction is ("a chronic brain disease") and is not ("Taking opioids for pain relief"). It goes on to explain that "[a]ddicts take opioids for other reasons, such as unbearable emotional problems. Taking opioids as prescribed for pain relief is not addiction." This publication is still available online.

An Endo publication, *Living with Someone with Chronic Pain*, stated, "Most health care providers who treat people with pain agree that most people do not develop an addiction problem." A similar statement appeared on the Endo website, www.opana.com, until at least April 2012.

In addition, a 2009 patient education publication, *Pain: Opioid Therapy*, funded by Endo and posted on *Painknowledge.com*, omitted addiction from the "common risks" of opioids, as shown below:



As with any medication, there are some side effects that are associated with opioid therapy. The most common side effects that occur with opioid use include the following:

- Constipation
- Drowsiness
- Confusion
- Nausea
- Itching
- Dizziness
- Shortness of breath

Your healthcare provider can help to address and, in some cases, prevent side effects that may occur as a result of opioid treatment. Less severe side effects, including nausea, itching, or drowsiness, typically go away within a few days without the need for further treatment. If you experience any side effects, you should let your healthcare provider know immediately.

Janssen's misrepresentations regarding addiction risk

Janssen likewise misrepresented the addiction risk of opioids on its websites and print materials. One website, *Let's Talk Pain*, states, among other things, that "the stigma of drug addiction and abuse" associated with the use of opioids stemmed from a "lack of understanding

about addiction." (Although Janssen described the website internally as an unbranded third-party program, it carried Janssen's trademark and copy approved by Janssen.)

The *Let's Talk Pain* website also perpetuated the concept of pseudoaddiction, associating patient behaviors such as "drug seeking," "clock watching," and "even illicit drug use or deception" with undertreated pain which can be resolved with "effective pain management." In August 2009, a "12 month review" of the *Let's Talk Pain* website manuscript confirmed that the website's contents included statements regarding pseudoaddiction and illustrated Janssen's control over the website and awareness of its contents.

A Janssen unbranded website, *PrescribeResponsibly.com*, states that concerns about opioid addiction are "overestimated" and that "true addiction occurs only in a small percentage of patients."

Janssen reviewed, edited, approved, and distributed a patient education guide entitled *Finding Relief: Pain Management for Older Adults*, which, as seen below, described as "myth" the claim that opioids are addictive, and asserted as fact that "[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain." Until recently, this guide was still available online.

Janssen's website for Duragesic included a section addressing "Your Right to Pain Relief" and a hypothetical patient's fear that "I'm afraid I'll become a drug addict." The website's response: "Addiction is relatively rare when patients take opioids appropriately."

According to an internal marketing assessment, Janssen sales representatives were trained to emphasize that Nucynta ER had fewer side effects than other opioids, though, upon information and belief, this was an untrue and unsubstantiated superiority claim.

Janssen also conducted a research study on prescribers regarding the visual aids for the marketing of Nucynta ER. Doctors reportedly were interested that Nucynta was described as appropriate for patients at risk for addiction and to avoid addictive narcotics for young people. Additionally, doctors identified the advantages of Nucynta, which included that it was potentially less addicting than other opioids and had a lower street value.

Janssen also published a patient guide, *Patient Booklet Answers to Your Questions– Duragesic*, which stated that "Addiction is relatively rare when patients take opioids appropriately."

Janssen recognized that this misrepresentation was particularly important to payors, who had a "negative" reaction to covering an addictive drug for a chronic condition for which non- narcotic drugs were available.

Cephalon's misrepresentations regarding addiction risk

Cephalon sponsored and facilitated the development of a guidebook, *Opioid Medications and REMS: A Patient's Guide*, which included claims that "patients without a history of abuse or a family history of abuse do not commonly become addicted to opioids." Similarly, Cephalon sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which taught that addiction is rare and limited to extreme cases of unauthorized dose escalations,

obtaining opioids from multiple sources, or theft.

For example, a 2003 Cephalon-sponsored CME presentation titled *Pharmacologic Management of Breakthrough or Incident Pain*, posted on Medscape in February 2003, teaches:

[C]hronic pain is often undertreated, particularly in the noncancer patient population. . . . The continued stigmatization of opioids and their prescription, coupled with often unfounded and self-imposed physician fear of dealing with the highly regulated distribution system for opioid analgesics, remains a barrier to effective pain management and must be addressed. Clinicians intimately involved with the treatment of patients with chronic pain recognize that the majority of suffering patients lack interest in substance abuse. In fact, patient fears of developing substance abuse behaviors such as addiction often lead to undertreatment of pain. The concern about patients with chronic pain becoming addicted to opioids during long-term opioid therapy may stem from confusion between physical dependence (tolerance) and psychological dependence (addiction) that manifests as drug abuse.

An internal "educational" document claimed that "in patients without personal or family history of substance abuse, addiction resulting from exposure to opioid therapy is uncommon." The document continued, "Like patients, caregivers may need reassurance that few people using opioids for a legitimate medical reason become addicted to the drug, and that physical dependence to a drug is easily overcome through scheduled dosing decreases . . . " Upon information and belief, this Cephalon "learning module" was used to train sales representatives for their interactions with prescribers.

Actavis's misrepresentations regarding addiction risk

Through its "Learn More about customized pain control with Kadian" material, Actavis

claimed that it is possible to become addicted to morphine-based drugs like Kadian, but that it is "less likely" to happen in those who "have never had an addiction problem." The piece goes on to advise that a need for a "dose adjustment" is the result of tolerance, and "not addiction."

Training for Actavis sales representatives deceptively minimizes the risk of addiction by: (i) attributing addiction to "predisposing factors" like family history of addiction or psychiatric disorders; (ii) repeatedly emphasizing the difference between substance dependence and substance abuse; and (iii) using the term pseudoaddiction, which, as described below, dismisses evidence of addiction as the undertreatment of pain and, dangerously, counsels doctors to respond to its signs with more opioids.

Actavis conducted a market study on takeaways from prescribers' interactions with Kadian sales representatives. The doctors had a strong recollection of the sales representatives' discussion of the low-abuse potential. Actavis' sales representatives' misstatements on the low- abuse potential was considered an important factor to doctors, and was most likely repeated and reinforced to their patients. Additionally, doctors reviewed visual aids that the Kadian sales representatives use during the visits, and Actavis noted that doctors associate Kadian with less abuse and no highs, in comparison to other opioids. Numerous marketing surveys of doctors in 2010 and 2012, for example, confirmed Actavis's messaging about Kadian's purported low addiction potential, and that it had less abuse potential than other similar opioids.

A guide for prescribers under Actavis's copyright deceptively represents that Kadian is more difficult to abuse and less addictive than other opioids. The guide includes the following statements:

"unique pharmaceutical formulation of KADIAN may offer some protection from extraction of morphine sulfate for intravenous use by illicit users," and KADIAN may be less likely to be

abused by health care providers and illicit users" because of "Slow onset of action," "Lower peak plasma morphine levels than equivalent doses of other formulations of morphine," "Long duration of action," and "Minimal fluctuations in peak to trough plasma levels of morphine at steady state." These statements convey both that (1) Kadian does not cause euphoria and therefore is less addictive and that (2) Kadian is less prone to tampering and abuse, even though Kadian was not approved by the FDA as abuse deterrent, and, upon information and belief, Actavis had no studies to suggest it was.

Mallinckrodt's misrepresentations regarding addiction risk

As described below, Mallinckrodt promoted its branded opioids Exalgo and Xartemis XR, and opioids generally, in a campaign that consistently mischaracterized the risk of addiction. Mallinckrodt did so through its website and sales force, as well as through unbranded communications distributed through the "C.A.R.E.S. Alliance" it created and led.

Mallinckrodt in 2010 created the C.A.R.E.S. (Collaborating and Acting Responsibly to Ensure Safety) Alliance, which it describes as "a coalition of national patient safety, provider and drug diversion organizations that are focused on reducing opioid pain medication abuse and increasing responsible prescribing habits." The "C.A.R.E.S. Alliance" itself is a service mark of Mallinckrodt LLC (and was previously a service mark of Mallinckrodt, Inc.) copyrighted and registered as a trademark by Covidien, its former parent company. Materials distributed by the C.A.R.E.S. Alliance, however, include unbranded publications that do not disclose a link to Mallinckrodt.

By 2012, Mallinckrodt, through the C.A.R.E.S. Alliance, was promoting a book titled *Defeat Chronic Pain Now!* This book is still available online. The false claims and misrepresentations in this book include the following statements:

"Only rarely does opioid medication cause a true addiction when prescribed appropriately to a chronic pain patient who does not have a prior history of addiction."

"It is currently recommended that every chronic pain patient suffering from moderate to severe pain be viewed as a potential candidate for opioid therapy."

"When chronic pain patients take opioids to treat their pain, they rarely develop a true addiction and drug craving."

"Only a minority of chronic pain patients who are taking long-term opioids develop tolerance."

"**The bottom line:** Only rarely does opioid medication cause a true addiction when prescribed appropriately to a chronic pain patient who does not have a prior history of addiction."

"Here are the facts. It is very uncommon for a person with chronic pain to become 'addicted' to narcotics IF (1) he doesn't have a prior history of any addiction and (2) he only takes the medication to treat pain."

"Studies have shown that many chronic pain patients can experience significant pain relief with tolerable side effects from opioid narcotic medication when taken daily and no addiction."

In a 2013 *Mallinckrodt Pharmaceuticals Policy Statement Regarding the Treatment of Pain and Control of Opioid Abuse*, which is still available online, Mallinckrodt stated that, "[s]adly, even today, pain frequently remains undiagnosed and either untreated or undertreated" and cites to a report that concludes that "the majority of people with pain use their prescription drugs properly, are not a source of misuse, and should not be stigmatized or denied access because of the misdeeds or carelessness of others."

Defendants' suggestions that the opioid epidemic is the result of bad patients who manipulate doctors to obtain opioids illicitly helped further their marketing scheme, but is at odds with the

facts. While there are certainly patients who unlawfully obtain opioids, they are a small minority. For example, patients who "doctor-shop"—i.e., visit multiple prescribers to obtain opioid prescriptions—are responsible for roughly 2% of opioid prescriptions. The epidemic of opioid addiction and abuse is overwhelmingly a problem of false marketing (and unconstrained distribution) of the drugs, not problem patients.

Defendants' efforts to trivialize the risk of addiction were, and remain, unsupported by scientific evidence. Studies have shown that at least 8-12%, and as many as 30- 40% of long-term users of opioids experience problems with addiction. According to one study, nearly 60% of patients who used opioids for 90 days continued to use opioids five years later. Addiction can result from the use of any opioid, "even at recommended dose" and the risk increases with chronic (more than three months) use. The CDC has emphasized that "continuing opioid therapy for 3 months substantially increases risk for opioid use disorder."

Falsehood #2: Signs of addiction are "pseudoaddiction," requiring more opioids

Defendants covered up the occurrence of addiction by attributing it to a made-up condition they called "pseudoaddiction." Signs of addiction, including shopping for doctors willing to newly write or refill prescriptions for opioids or seeking early refills, actually reflected undertreated pain that should be addressed with more opioids—the medical equivalent of fighting fire by adding fuel.

Purdue, through its unbranded imprint *Partners Against Pain*, promoted the concept of pseudoaddiction through at least 2013 on its website. It disseminated the Definitions Related to the Use of Opioids for the Treatment of Pain section of an American Pain Society ("APS") consensus statement through the website, where APS, who received funding from Defendants, defined pseudoaddiction in the same terms endorsed by Purdue:

Physical dependence, tolerance, and addiction are discrete and different phenomena that are often confused . . . Pseudoaddiction is a term which has been used to describe patient behaviors that may occur when pain is undertreated. Patients with unrelieved pain may become focused on obtaining medications, may 'clock watch,' and may otherwise seem inappropriately 'drug seeking.' Even such behaviors as illicit drug use and deception can occur in the patient's efforts to obtain relief. Pseudoaddiction can be distinguished from true addiction in that the behaviors resolve when pain is effectively treated. . . . A patient who is physically dependent on opioids may sometimes continue to use these [medications] despite resolution of pain only to avoid withdrawal. Such use does not necessarily reflect addiction.

The Federation of State Medical Boards ("FSMB"), a trade organization representing state medical boards, finances opioid- and pain-specific programs through grants from Defendants. A 2004 version of the FSMB *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain* ("FSMB Guidelines"), and the 2007 book adapted from them, *Responsible Opioid Prescribing*, advanced the concept of pseudoaddiction.

Responsible Opioid Prescribing was sponsored by Purdue, Endo, and Teva. The FSMB website described the book as the "leading continuing medical education (CME) activity for prescribers of opioid medications." In all, more than 163,000 copies of *Responsible Opioid Prescribing* were distributed nationally.

Janssen sponsored, funded, and edited the *Let's Talk Pain* website, which in 2009 stated: "pseudoaddiction . . . refers to patient behaviors that may occur when *pain is under- treated* . . . . Pseudoaddiction is different from true addiction because such behaviors can be resolved with effective pain management." This website was accessible online until May 2012.

Endo sponsored a National Initiative on Pain Control (NIPC) CME program in 2009 titled

Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia, which promoted pseudoaddiction by teaching that a patient's aberrant behavior was the result of untreated pain. Endo substantially controlled NIPC, an initiative run by the APF, by funding NIPC projects; developing, specifying, and reviewing its content; and distributing NIPC materials. APF internal documents show that APF viewed the NIPC as an "opportunity to generate new revenue" given Endo's funding commitment.

Defendants also promoted the concept of pseudoaddiction through Dr. Russell Portenoy, a leading KOL for the Defendants. In doing so, he popularized the concept and falsely claimed that pseudoaddiction is substantiated by scientific evidence.

The FAQs section of *pain-topics.org*, a now-defunct website to which Mallinckrodt provided funding, also contained misleading information about pseudoaddiction. Specifically, the website advised providers to "keep in mind" that signs of potential drug diversion, rather than signaling "actual" addiction, "may represent pseudoaddiction," which the website described as behavior that occurs in patients when pain is "undertreated" and includes patients becoming "very focused on obtaining opioid medications and may be erroneously perceived as 'drug seeking.'"

The CDC Guideline for prescribing opioids for chronic pain, a "systematic review of the best available evidence" by a panel excluding experts with conflicts of interest, rejects the concept of pseudoaddiction. The Guideline nowhere recommends that opioid doses be increased if a patient is not experiencing pain relief. To the contrary, the Guideline explains that "[p]atients who do not experience clinically meaningful pain relief early in treatment . . . are unlikely to experience pain relief with longer-term use," and that physicians should "reassess[] pain and function within 1 month" in order to decide whether to "minimize risks of long-term opioid use

by discontinuing opioids" because the patient is "not receiving a clear benefit."

Falsehood #3: To the extent there is a risk of addiction, it can be easily identified and managed

Defendants falsely instructed prescribers and patients that screening tools, patient contracts, urine drug screens, and similar strategies allow health care providers to safely prescribe opioids to patients, including patients predisposed to addiction, and failed to disclose the lack of evidence that these strategies actually work to mitigate addiction risk. By using screening tools, these Defendants advised doctors that they could identify patients likely to become addicted and safely prescribe to everyone else.

Such misrepresentations regarding safe opioid prescribing made health care providers more comfortable prescribing opioids to their patients and patients more comfortable starting opioid therapy. These misrepresentations were especially insidious because Defendants aimed them at general practitioners and family doctors who lack the time and expertise to closely manage higher-risk patients on opioids. Moreover, these misrepresentations allowed doctors to believe opioid addiction was the result of other prescribers failing to rigorously manage and weed out problem patients, not a risk inherent to the drugs.

These Defendants conveyed these safe prescribing messages in nationally distributed marketing materials. A catalogue distributed by Purdue to prescribers across the country and, on information and belief, in the City, included information on screening tools. On information and belief, none of the Defendants disclosed the lack of evidence for efficacy of these tools.

Defendants also promoted screening tools as a reliable means to manage addiction risk in CME programs and scientific conferences, which would have been attended by or were available online, to Huntington prescribers.

For example, Purdue sponsored a 2011 CME program titled Managing Patient's Opioid Use: Balancing the Need and Risk. This presentation deceptively instructed prescribers that screening tools, patient agreements, and urine tests prevented "overuse of prescriptions" and "overdose deaths." Purdue also funded a 2012 CME program called Chronic Pain Management and Opioid Use: Easing Fears, Managing Risks, and Improving Outcomes. The presentation deceptively instructed doctors that, through the use of screening tools, more frequent refills, and other techniques, even high-risk patients showing signs of addiction could be treated with opioids.

Purdue used its involvement in the College on the Problems of Drug Dependence ("CPDD"), which promotes scientific research and professional development to support addiction prevention professionals, to promote the idea that addiction risk can be managed. A Purdue employee served on the CPDD board of directors. Purdue presented a disproportionate number of talks—with very different messages from non-Purdue talks—at CPDD conferences. One of Purdue's consistent themes is that "bad apple" patients, not opioids, are the source of the opioid crisis, and that once those patients are identified doctors can safely prescribe opioids without a risk of addiction. Hundreds of addiction treatment specialists from across the country and, upon information and belief, from the City, attended these conferences.

Endo paid for a 2007 supplement in the Journal of Family Practice written by a doctor who became a member of Endo's speakers' bureau (doctors paid to give talks, typically reserved for the largest prescribers) in 2010. The supplement, entitled *Pain Management Dilemmas in Primary Care: Use of Opioids*, emphasized the effectiveness of screening tools, claiming that patients at high risk of addiction could safely receive opioid therapyusing a "maximally structured approach" involving toxicology screens and pill counts.

The CDC Guideline confirmed the falsity of Defendants' claims about the utility of patient screening and management strategies in managing addiction risk. The Guideline notes that there are no studies assessing the effectiveness of risk mitigation strategies— such as screening tools or patient contracts—"for improving outcomes related to overdose, addiction, abuse, or misuse." The CDC Guideline recognized that available risk screening tools "show insufficient accuracy for classification of patients as at low or high risk for [opioid] abuse or misuse" and counseled that doctors "should not overestimate the ability of these tools to rule out risks from long-term opioid therapy."

Falsehood #4: Opioid withdrawal can be avoided by tapering

Purdue's profits, and, upon information and belief, the profits of the other Defendants, depend on keeping patients on opioids on an ongoing basis. According to internal documents, 87% of Purdue's OxyContin business is driven by continuing prescriptions.

Thus, recurring prescriptions to chronic pain patients is a key component of Purdue's business model.

To convince prescribers and patients that opioids should be used to treat chronic pain, Defendants had to persuade them of a significant upside to long-term opioid use. Assessing existing evidence, the CDC Guideline found that there is "insufficient evidence to determine the long-term benefits of opioid therapy for chronic pain." In fact, the CDC found that "[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later (with most placebo-controlled randomized trials ≤ 6 weeks in duration)" and that other treatments were more or equally beneficial and less harmful than long-term opioid use. The FDA, too, has recognized the lack of evidence to support long-term opioid use. In 2013, the FDA stated that it was "not aware of

adequate and well- controlled studies of opioids use longer than 12 weeks." As a result, the CDC recommends that opioids not be used in the first instance and for treatment of chronic pain; rather, opioids should be used only after prescribers have exhausted alternative treatments.

Nevertheless, upon information and belief, Defendants touted the purported benefits of long-term opioid use, while falsely and misleadingly suggesting that these benefits were supported by scientific evidence.

In addition, two prominent professional medical membership organizations, the American Pain Society ("APS") and the American Academy of Pain Medicine ("AAPM"), each received substantial funding from Defendants. According to a letter from U.S. Senate Committee on Finance Ranking Member Ron Wyden to Secretary Thomas Price of the U.S. Department of Health & Human Services, as recently as May 2017, the Corporate Council of AAPM included Endo, Janssen, Purdue and Teva, along with several other pharmaceutical drug companies. Upon information and belief, Defendants exercised considerable influence over their work on opioids. Both organizations issued a consensus statement in 1997, *The Use of Opioids for the Treatment of Chronic Pain*, which endorsed opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low. The co- author of the statement, Dr. David Haddox, was at the time a paid speaker for Purdue and later became a senior executive for the company. KOL Dr. Portenoy was the sole consultant. The consensus statement remained on AAPM's website until 2011 and was only removed from AAPM's website after a doctor complained.

A past president of the AAPM, Dr. Scott Fishman, who also served as a KOL for Defendants, stated that he would place the organization "at the forefront" of teaching that "the risks of

addiction are . . . small and can be managed."

AAPM and APS issued treatment guidelines in 2009 ("AAPM/APS Guidelines"), which continued to recommend the use of opioids to treat chronic pain. Treatment guidelines, like the AAPM/APS Guidelines, were particularly important to Defendants in securing acceptance for opioid therapy. They are relied upon by doctors, especially general practitioners and family doctors who have no specific training in treating chronic pain. Six of the twenty-one panel members who drafted the AAPM/APS Guidelines received support from Purdue, eight from Teva, nine from Janssen, and ten from Endo.

The AAPM/APS Guidelines promote opioids as "safe and effective" for treating chronic pain. The panel made "strong recommendations" despite "low quality of evidence" and concluded that the risk of addiction is manageable for patients, even with a prior history of drug abuse. One panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and founder of the Michigan Headache & Neurological Institute, resigned from the panel because of his concerns that the Guidelines were influenced by contributions that drug companies, including Purdue, Endo, Janssen, and Teva, made to the sponsoring organizations and committee members.

Dr. Gilbert Fanciullo, now retired as a professor at Dartmouth College's Geisel School of Medicine, who served on the AAPM/APS Guidelines panel, has since described them as "skewed" by drug companies and "biased in many important respects," including the high presumptive maximum dose, lack of suggested mandatory urine toxicology testing, and claims of a low risk of addiction.

The AAPM/APS Guidelines are still available online, were reprinted in the *Journal of Pain*, and have influenced not only treating physicians, but also the body of scientific evidence on

opioids. According to Google Scholar, they have now been cited at least 1,647 times in academic literature. These Guidelines were available to Huntington prescribers.

Purdue specifically marketed its opioids for chronic pain conditions such as low back pain and osteoarthritis, using "vignettes," or patient exemplars, illustrating the use of opioids to treat patients with these conditions, and inviting doctors to identify patients with these conditions as appropriate candidates for its opioids. Purdue also acknowledged its strategy to encourage prescribers to switch patients from nonsteroidal anti-inflammatory drugs ("NSAIDs," over-the-counter, non-narcotic pain relievers such as ibuprofen) through articles in "reputable journals" such as AAPM's and "hearing from respected physicians."

Purdue also published misleading studies to enhance the perception that opioids are effective long-term for chronic pain conditions. One study asserts that OxyContin is safe and effective for the chronic pain condition osteoarthritis. The study, sponsored by Purdue, involved providing oxycodone for 30 days, and then randomizing participants and providing a placebo, an immediate release oxycodone with acetaminophen (like Percocet), or OxyContin. Only 107 of the 167 patients went on to the second phase of the study, and most who withdrew left because of adverse events (nausea, vomiting, drowsiness, dizziness, or headache) or ineffective treatment. Despite relating to a chronic condition, opioids were provided only short-term. The authors even acknowledge that the "results . . . should be confirmed in trials of longer duration to confirm the role of opioids in a chronic condition such as OA [osteoarthritis]." Yet, the authors conclude that "[t]his clinical experience shows that opioids were well tolerated with only rare incidence of addiction and that tolerance to the analgesic effects was not a clinically significant problem when managing patients with opioids long-term." This statement is not supported by the data—a substantial proportion of patients dropped out because of adverse

effects, there was no reported data regarding addiction, and the study was not long-term.

Teva deceptively marketed its opioids Actiq and Fentora for chronic pain even though the FDA has expressly limited their use to the treatment of cancer pain in opioid- tolerant individuals.

Both Actiq and Fentora are extremely powerful fentanyl-based opioids. Neither is approved for or has been shown to be safe or effective for chronic pain. Indeed, the FDA expressly prohibited Teva from marketing Actiq for anything but cancer pain, and refused to approve Fentora for the treatment of chronic pain because of the potential harm, including the high risks of "serious and life-threatening adverse events" and abuse—which are greatest in non-cancer patients. The FDA also issued a Public Health Advisory in 2007 emphasizing that Fentora should only be used for cancer patients who are opioid-tolerant and should not be used for any other conditions, such as migraines, post-operative pain, or pain due to injury.

Despite this, Teva has conducted a well-funded and deceptive campaign to promote Actiq and Fentora for chronic pain and other non-cancer conditions for which it was not approved, appropriate, or safe. This campaign included the use of CMEs, speaker programs, KOLs, and journal supplements to give doctors the false impression that Actiq and Fentora are safe and effective for treating non-cancer pain, without disclosing the lack of evidence or the FDA's rejection of their use for chronic pain.

For example, Teva paid to have a CME it sponsored, *Opioid-Based Management of Persistent and Breakthrough Pain*, published in a supplement of Pain Medicine News in 2009. The CME instructed doctors that "clinically, broad classification of pain syndromes as either cancer- or noncancer-related has limited utility" and recommended Actiq and Fentora for patients with chronic pain. The CME is still available online.

Teva's sales representatives set up hundreds of speaker programs for doctors, including many non-oncologists, which promoted Actiq and Fentora for the treatment of non-cancer pain.

In December 2011, Teva widely disseminated a journal supplement entitled *"Special Report: An Integrated Risk Evaluation and Mitigation Strategy for Fentanyl Buccal Tablet (FENTORA) and Oral Transmucosal Fentanyl Citrate (ACTIQ)"* to Anesthesiology News, Clinical Oncology News, and Pain Medicine News—three publications that are sent to thousands of anesthesiologists and other medical professionals nationally, including, upon information and belief, in the City. The Special Report openly promotes Fentora for "multiple causes of pain," and not just cancer pain.

Teva's deceptive marketing gave doctors and patients the false impression that Actiq and Fentora were not only safe and effective for treating chronic pain, but also were approved by the FDA for such uses.

On December 28, 2011, the FDA mandated a Risk Evaluation and Mitigation Strategy (REMS) for the class of products for which Teva's Actiq and Fentora belong, Transmucosal Immediate Release Fentanyl (TIRF). The TIRF REMS programs include mandatory patient and prescriber enrollment forms, as well as certification requirements for prescribers. The forms are not comprehensive and do not, for instance, disclosethat addiction can develop when the medications are used as prescribed, nor do they disclose that risks are greatest at higher doses—and patients must already be taking high doses of opioids to be prescribed Actiq and Fentora.

Falsehood #5: Long-term opioid use improves functioning

Defendants also claimed—without evidence—that long-term opioid use would help patients resume their lives and jobs.

Defendants' materials that, upon information and belief, were distributed or made available in the City, reinforced this message. The 2011 publication *A Policymaker's Guide* falsely claimed that "multiple clinical studies have shown that opioids are effective in improving" "[d]aily function" and "[o]verall health-related quality of life for people with chronic pain." A series of medical journal advertisements for OxyContin in 2012 presented "Pain Vignettes"—case studies featuring patients with pain conditions persisting over several months—that implied functional improvement. For example, one advertisement described a "writer with osteoarthritis of the hands" and implied that OxyContin would help him work more effectively. Similarly, starting in at least May of 2011, Endo distributed and made available on its website, opana.com, a pamphlet promoting Opana ER with photographs depicting patients with physically demanding jobs like construction worker and chef, misleadingly implying that the drug would provide long-term pain-relief and functional improvement.

Additional illustrative examples are described below:

Janssen sponsored and edited a patient education guide entitled Finding Relief: Pain Management for Older Adults (2009), which states as "a fact" that "opioids may make it easier for people to live normally." The guide lists expected functional improvements from opioid use, including sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs and states that "[u]sed properly, opioid medications can make it possible for people with chronic pain to 'return to normal.'"

Responsible Opioid Prescribing (2007), sponsored and distributed by Teva, Endo and Purdue, taught that relief of pain by opioids, by itself, improved patients' function. The book remains for sale online.

Purdue and Teva sponsored APF's Treatment Options: A Guide for People Living with Pain

(2007), which counseled patients that opioids "give [pain patients] a quality of life we deserve." The guide was available online until APF shut its doors in May 2012.

Endo's NIPC website painknowledge.com claimed in 2009 that with opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse." Elsewhere, the website touted improved quality of life (as well as "improved function") as benefits of opioid therapy. The grant request that Endo approved for this project specifically indicated NIPC's intent to make claims of functional improvement, and Endo closely tracked visits to the site.

Endo was the sole sponsor, through NIPC, of a series of CMEs titled Persistent Pain in the Older Patient, which claimed that opioid therapy has been "shown to reduce pain and improve depressive symptoms and cognitive functioning." The CME was disseminated via webcast.

Mallinckrodt followed suit, stating on its website, in a section on "responsible use" of opioids, claims that "[t]he effective pain management offered by our medicines helps enable patients to stay in the workplace, enjoy interactions with family and friends, and remain an active member of society."

Likewise, Defendants' claims that long-term use of opioids improves patient function and quality of life are unsupported by clinical evidence. As noted above, there are no controlled studies of the use of opioids beyond 16 weeks, and there is no evidence that opioids improve patients' pain and function long-term. On the contrary, the available evidence indicates opioids are not effective to treat chronic pain, and may worsen patients' health and pain. Increasing the duration of opioid use is strongly associated with an increasing prevalence of mental health conditions (depression, anxiety, post-traumatic stress disorder, and substance abuse), increased

psychological distress, and greater health care utilization.

As one pain specialist observed, "opioids may work acceptably well for a while, but over the long term, function generally declines, as does general health, mental health, and social functioning. Over time, even high doses of potent opioids often fail to control pain, and these patients are unable to function normally." Studies of patients with lower back pain and migraine headaches, for example, have consistently shown that patients experienced deteriorating function over time, as measured by ability to return to work, physical activity, pain relief, rates of depression, and subjective quality-of-life measures. Analyses of workers' compensation claims have found that workers who take opioids are almost four times more likely to reach costs over $100,000, stemming from greater side effects and slower returns to work. According to these studies, receiving an opioid for more than seven days also increased patients' risk of being on work disability one year later.

The FDA and other federal agencies have, for years, made clear the lack of evidence for claims that the use of opioids for chronic pain improves patients' function and quality of life. The CDC Guideline, following a "systematic review of the best available evidence," concluded that "[w]hile benefits for pain relief, function and quality of life with long-term opioid use for chronic pain are uncertain, risks associated with long-term opioid use are clearer and significant." According to the CDC, "for the vast majority of patients, the known, serious, and too-often-fatal risks far outweigh the unproven and transient benefits [of opioids for chronic pain]."

Falsehood #6: Alternative forms of pain relief pose greater risks than opioids

In materials Defendants produced, sponsored, or controlled, these Defendants omitted known risks of opioid therapy and emphasized or exaggerated risks of competing products so that

prescribers and patients would be more likely to choose opioids and would favor opioids over other therapies such as over-the-counter acetaminophen or NSAIDs. None of these claims were corroborated by scientific evidence. In fact, several studies have shown that ibuprofen and acetaminophen taken together are better than opioids at relieving pain such as dental pain, low back pain, and moderate acute traumatic pain.

In addition to failing to disclose in promotional materials the risks of addiction, abuse, overdose, and death, Defendants routinely ignored other risks, such as hyperalgesia, a "known serious risk associated with opioid analgesic therapy," in which the patient becomes more sensitive to pain over time; hormonal dysfunction; decline in immune function; mental clouding, confusion, and dizziness; increased falls and fractures in the elderly; neonatal abstinence syndrome (when an infant exposed to opioids prenatally withdraws from the drugs after birth); and potentially fatal interactions with alcohol or benzodiazepines, which are used to treat post-traumatic stress disorder and anxiety (conditions that often accompany chronic pain symptoms).

Purdue and Teva sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which counseled patients that opioids differ from NSAIDs in that they have "no ceiling dose" and are therefore the most appropriate treatment for severe pain. The publication inaccurately attributes 10,000 to 20,000 deaths annually to NSAIDs (the actual figure is approximately 3,200—far fewer than from opioids). This publication also warned that risks of NSAIDs increase if "taken for more than a period of months," with no corresponding warning about opioids.

APF's *Exit Wounds*, sponsored by Purdue and Endo and aimed at veterans, omits warnings of the potentially fatal risk of interactions between opioids and benzodiazepines, a class of drug

commonly prescribed to veterans with post-traumatic stress disorder. This book is available from Amazon.com and other retailers.

Purdue and Endo sponsored a CME program, *Overview of Management Options*, published by the American Medical Association in 2003, 2007, 2010, and 2013, and discussed further below. The CME was edited by Dr. Russell Portenoy, among others, and taught that NSAIDs and other drugs, but not opioids, are unsafe at high doses.

Defendants frequently contrasted the lack of a ceiling dosage for opioids with the risks of NSAIDs. These Defendants deceptively describe the risks from NSAIDs while failing to disclose the risks from opioids. (*See e.g.*, *Case Challenges in Pain Management: Opioid Therapy for Chronic Pain* (Endo) [describing massive gastrointestinal bleeds from long-term use of NSAIDs and recommending opioids]; *Finding Relief: Pain Management for Older Adults* (Janssen) [NSAIDs caused kidney or liver damage and increased risk of heart attack and stroke, versus opioids, which cause temporary "upset stomach or sleepiness" and constipation].)

These omissions are significant and material to patients and prescribers. A Cochrane Collaboration review of evidence relating to the use of opioids for chronic pain found that 22.9% of patients in opioid trials dropped out before the study began because of the "adverse effects" of opioids.

Again, Defendants' misrepresentations were effective. A study of 7.8 million doctor visits nationwide between 2000 and 2010 found that opioid prescriptions increased from 11.3% to 19.6% of visits while NSAID and acetaminophen prescriptions fell from 38% to 29%. The CDC reports that the quantity of opioids dispensed per capita tripled from 1999 to 2015.

Falsehood #7: Opioid doses can be increased without limit or greater risks

Defendants falsely claimed to prescribers and consumers that opioids could be taken in ever-increasing strengths to obtain pain relief, without disclosing that higher doses increased the risk of addiction and overdose. This was particularly important because patients on opioids for more than a brief period develop tolerance, requiring increasingly high doses to achieve pain relief. These Defendants needed to generate a comfort level among doctors to ensure the doctors maintained patients on the drugs even at the high doses that became necessary. Further, as described in more detail below, Purdue encouraged doctors to prescribe higher doses, rather than prescribe OxyContin more frequently than twice-a-day—despite knowing that OxyContin frequently did not provide 12 hours of relief.

Purdue-sponsored publications and CMEs available online also misleadingly suggested that higher opioid doses carried no added risk.

Through at least June 2015, Purdue's *In the Face of Pain* website promoted the notion that if a patient's doctor did not prescribe a sufficient dose of opioids, the patient should see different doctors until finding a doctor who would.

A Policymaker's Guide, the 2011 publication on which, upon information and belief, Purdue collaborated with APF, taught that dose escalations are "sometimes necessary," but it did not disclose the risks from high dose opioids. Until recently, this publication was still available online.

The Purdue-sponsored CME, *Overview of Management Options*, discussed above, again instructed physicians that NSAIDs (like ibuprofen) are unsafe at high doses (because of risks to patients' kidneys), but it did not disclose risks from opioids at high doses.

Endo sponsored a website, painknowledge.com, which claimed in 2009 that opioid dosages may

be increased until "you are on the right dose of medication for your pain."

Endo distributed a pamphlet edited by Dr. Russell Portenoy entitled *Understanding Your Pain: Taking Oral Opioid Analgesics*, which appeared on Endo's website. In Q&A format, it asked "If I take the opioid now, will it work later when I really need it?" The response is, "The dose can be increased. . . . You won't 'run out' of pain relief."

Janssen sponsored a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which was distributed by its sales force. This guide listed dosage limitations as "disadvantages" of other pain medicines but omitted any discussion of risks of increased opioid dosages.

These claims conflict with the scientific evidence. Patients receiving high doses of opioids (*e.g.*, doses greater than 100 mg morphine equivalent dose ("MED") per day) as part of long-term opioid therapy are three to nine times more likely to suffer overdose from opioid-related causes than those on low doses. As compared to available alternative pain remedies, scholars have suggested that tolerance to the respiratory depressive effects of opioids develops at a slower rate than tolerance to opioids' analgesic effects. Accordingly, the practice of continuously escalating doses to match pain tolerance can, in fact, lead to overdose even where opioids are taken as recommended.

The CDC Guideline concludes that the "[b]enefits of high-dose opioids for chronic pain are not established" while "there is an increased risk for serious harms related to long-term opioid therapy that appears to be dose-dependent." That is why the CDC advises doctors to "avoid increasing doses" above 90 mg MED.

Falsehood #8: OxyContin provides twelve hours of pain relief

To convince prescribers and patients to use OxyContin, Purdue misleadingly promoted the drug as providing 12 continuous hours of pain relief with each dose. In reality, OxyContin does not last for 12 hours in many patients, a fact Purdue has known since the product's launch.

OxyContin has been FDA-approved for twice daily—"Q12"—dosing frequency since its debut in 1996. Purdue sought that dosing frequency in order to maintain a competitive advantage over more frequently dosed opioids. Even so, Purdue has gone well beyond the label's instructions to take OxyContin every 12 hours. Purdue has affirmatively claimed in its general marketing, including, upon information and belief, to prescribers in the City, that OxyContin lasts for 12 hours and that this is a key advantage of OxyContin, implying that most or all patients would in fact experience continuous pain relief for the full 12 hour dose period. Purdue has also failed to disclose that OxyContin fails to provide 12 hours of pain relief to many patients. These misrepresentations, which Purdue continues to make, are particularly dangerous because inadequate dosing helps fuel addiction, as explained below.

From the outset, Purdue leveraged 12-hour dosing to promote OxyContin as providing continuous, round-the-clock pain relief with the convenience of not having to wake to take a third or fourth pill. The 1996 press release for OxyContin touted 12-hour dosing as providing "smooth and sustained pain control all day and all night." But the FDA has never approved such a marketing claim. To the contrary, the FDA found in 2008, in response to a Citizen Petition by the Connecticut Attorney General, that a "substantial number" of chronic pain patients taking OxyContin experienced "end of dose failure"—*i.e.,* little or no pain relief at the end of the dosing period.

Moreover, Purdue itself long has known, dating to its development of OxyContin, that the drug wears off well short of 12 hours in many patients. In one early Purdue clinical trial, a third of

patients dropped out because the treatment was ineffective. Researchers changed the rules to allow patients to take supplemental painkillers—"rescue doses"—in between OxyContin doses. In another study, most patients used rescue medication, and 95% resorted to it at least once. In other research conducted by Purdue, the drug wore off in under 6 hours in 25% of patients and in under 10 hours in more than 50%.

End-of-dose failure renders OxyContin even more dangerous because patients begin to experience withdrawal symptoms, followed by a euphoric rush with their next dose—a cycle that fuels a craving for OxyContin. For this reason, Dr. Theodore Cicero, a neuropharmacologist at the Washington University School of Medicine in St. Louis, has called OxyContin's 12-hour dosing "the perfect recipe for addiction." Many patients will exacerbate this cycle by taking their next dose ahead of schedule or resorting to a rescue dose of another opioid, increasing the overall amount of opioids they are taking.

Purdue has remained committed to 12-hour dosing because it is key to OxyContin's market dominance and comparatively high price; without this advantage, the drug had little to offer over less expensive, short-acting opioids. In a 2004 letter to the FDA, Purdue acknowledged that it had not pursued approval to allow more frequent dosing in the label (*e.g.,* every 8 hours) because 12-hour dosing was "a significant competitive advantage."

While Purdue's commitment to marketing opioids as a 12-hour drug made it more addictive, Purdue falsely promoted OxyContin as providing "steady state" relief and less likely than other opioids to create a cycle of crash and cravings that fueled addiction and abuse.

Promotion of 12-hour dosing, without disclosing its limitations, is misleading because it implies that the pain relief supplied by each dose lasts 12 hours. FDA approval of OxyContin for 12-hour dosing does not give Purdue license to misrepresent the duration of pain relief it

provides to patients; moreover, Purdue had a responsibility to correct its label to reflect appropriate dosing and to disclose to prescribers what it knew about OxyContin's actual duration, but disregarded that responsibility in its pursuit of a marketing advantage.

Purdue was also aware of some physicians' practice of prescribing OxyContin more frequently than 12 hours—a common occurrence. Purdue's promoted solution to this problem was to increase the dose, rather than the frequency, of prescriptions, even though higher dosing carries its own risks. According to a CDC clinical evidence review, higher opioid doses are related to increased risks of motor vehicle injury, opioid use disorder, and overdoses, and the increased risk increases in a dose-dependent manner. With higher doses, patients experience higher highs and lower lows, increasing their craving for their next pill. Nationwide, based on an analysis by the *Los Angeles Times*, more than 52% of patients taking OxyContin longer than three months are on doses greater than 60 milligrams per day—which converts to the 90 MED that the CDC Guideline urges prescribers to "avoid" or "carefully justify."

G. **The Defendants Disseminated Their Misleading Messages about Opioids Through Multiple Channels**

The Defendants' false marketing campaign not only targeted the medical community who had to treat chronic pain, but also patients who experience chronic pain.

The Defendants utilized various channels to carry out their marketing scheme of targeting the medical community and patients with deceptive information about opioids: (1) "Front Groups" with the appearance of independence from the Defendants; (2) so- called "key opinion leaders" ("KOLs"), that is, doctors who were paid by the Defendants to promote their pro-opioid message; (3) CME programs controlled and/or funded by the Defendants; (4) branded advertising; (5) unbranded advertising; (6) publications; direct, targeted communications with

prescribers by sales representatives or "detailers"; and speakers bureaus and programs.

H. **The Defendants Directed Front Groups to Deceptively Promote Opioid Use**

Patient advocacy groups and professional associations also became vehicles to reach prescribers, patients, and policymakers. Defendants exerted influence and effective control over the messaging by these groups by providing major funding directly to them, as well as through KOLs who served on their boards. These "Front Groups" put out patient education materials, treatment guidelines and CMEs that supported the use of opioids for chronic pain, overstated their benefits, and understated their risks. Defendants funded these Front Groups in order to ensure supportive messages from these seemingly neutral and credible third parties, and their funding did, in fact, ensure such supportive messages—often at the expense of their own constituencies.

"Patient advocacy organizations and professional societies like the Front Groups 'play a significant role in shaping health policy debates, setting national guidelines for patient treatment, raising disease awareness, and educating the public.'" "Even small organizations—with 'their large numbers and credibility with policymakers and the public'—have 'extensive influence in specific disease areas.' Larger organizations with extensive funding and outreach capabilities 'likely have a substantial effect on policies relevant to their industry sponsors.'" Indeed, the U.S. Senate's report, *Fueling an Epidemic: Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups*, which arose out of a 2017 Senate investigation and, drawing on disclosures from Purdue, Janssen, and other opioid manufacturers, "provides the first comprehensive snapshot of the financial connections between opioid manufacturers and advocacy groups and professional societies operating in the area of opioids policy," found that the Defendants made millions of dollars of contributions to various

Front Groups.

The Defendants also "made substantial payments to individual group executives, staff members, board members, and advisory board members" affiliated with the Front Groups subject to the Senate Committee's study.

As the Senate *Fueling an Epidemic* Report found, the Front Groups "amplified or issued messages that reinforce industry efforts to promote opioid prescription and use, including guidelines and policies minimizing the risk of addiction and promoting opioids for chronic pain." They also "lobbied to change laws directed at curbing opioid use, strongly criticized landmark CDC guidelines on opioid prescribing, and challenged legal efforts to hold physicians and industry executives responsible for overprescribing and misbranding."

The Defendants took an active role in guiding, reviewing, and approving many of the false and misleading statements issued by the Front Groups, ensuring that Defendants were consistently in control of their content. By funding, directing, editing, approving, and distributing these materials, Defendants exercised control over and adopted their false and deceptive messages and acted in concert with the Front Groups and through the Front groups, with each other to deceptively promote the use of opioids for the treatment of chronic pain.

American Pain Foundation

The most prominent of the Front Groups was the American Pain Foundation ("APF"). While APF held itself out as an independent patient advocacy organization, in reality it received 90% of its funding in 2010 from the drug and medical-device industry, including from defendants Purdue, Endo, Janssen and Cephalon. APF received more than $10 million in funding from opioid manufacturers from 2007 until it closed its doors in May 2012. By 2011, APF was

entirely dependent on incoming grants from Defendants Purdue, Cephalon, Endo, and others to avoid using its line of credit. Endo was APF's largest donor and provided more than half of its $10 million in funding from 2007 to 2012.

For example, APF published a guide sponsored by Cephalon and Purdue titled *Treatment Options: A Guide for People Living with Pain*, and distributed 17,200 copies of this guide in one year alone, according to its 2007 annual report. This guide contains multiple misrepresentations regarding opioid use which are discussed below.

APF also developed the National Initiative on Pain Control ("NIPC"), which ran a facially unaffiliated website, *www.painknowledge.com*. NIPC promoted itself as an education initiative led by its expert leadership team, including purported experts in the pain management field. NIPC published unaccredited prescriber education programs (accredited programs are reviewed by a third party and must meet certain requirements of independence from pharmaceutical companies), including a series of "dinner dialogues." But it was Endo that substantially controlled NIPC, by funding NIPC projects, developing, specifying, and reviewing its content, and distributing NIPC materials. Endo's control of NIPC was such that Endo listed it as one of its "professional education initiative[s]" in a plan Endo submitted to the FDA. Yet, Endo's involvement in NIPC was nowhere disclosed on the website pages describing NIPC or *www.painknowledge.org.* Endo estimated it would reach 60,000 prescribers through NIPC.

APF was often called upon to provide "patient representatives" for the Defendants' promotional activities, including for Purdue's "Partners Against Pain" and Janssen's "Let's Talk Pain." Although APF presented itself as a patient advocacy organization, it functioned largely as an advocate for the interests of the Defendants, not patients. As Purdue told APF in 2001, the basis of a grant to the organization was Purdue's desire to strategically align its

investments in nonprofit organizations that share [its] business interests.

In practice, APF operated in close collaboration with Defendants, submitting grant proposals seeking to fund activities and publications suggested by Defendants and assisting in marketing projects for Defendants.

This alignment of interests was expressed most forcefully in the fact that Purdue hired APF to provide consulting services on its marketing initiatives. Purdue and APF entered into a "Master Consulting Services" Agreement on September 14, 2011. That agreement gave Purdue substantial rights to control APF's work related to a specific promotional project. Moreover, based on the assignment of particular Purdue "contacts" for each project and APF's periodic reporting on their progress, the agreement enabled Purdue to be regularly aware of the misrepresentations APF was disseminating regarding the use of opioids to treat chronic pain in connection with that project. The agreement gave Purdue—but not APF—the right to end the project (and, thus, APF's funding) for any reason. Even for projects not produced during the terms of this Agreement, the Agreement demonstrates APF's lack of independence and willingness to harness itself to Purdue's control and commercial interests, which would have carried across all of APF's work.

APF's Board of Directors was largely comprised of doctors who were on the Defendants' payrolls, either as consultants or speakers at medical events. The close relationship between APF and the Defendants demonstrates APF's clear lack of independence, in its finances, management, and mission, and its willingness to allow Defendants to control its activities and messages supports an inference that each Defendant that worked with it was able to exercise editorial control over its publications—even when Defendants' messages contradicted APF's internal conclusions. For example, a roundtable convened by APF and funded by Endo also

acknowledged the lack of evidence to support opioid therapy. APF's formal summary of the meeting notes concluded that: "[An] important barrier[] to appropriate opioid management [is] the lack of confirmatory data about the long-term safety and efficacy of opioids in non-cancer chronic pain, amid cumulative clinical evidence."

In May 2012, the U.S. Senate Finance Committee began looking into APF to determine the links, financial and otherwise, between the organization and the manufacturers of opioid painkillers. Within days of being targeted by the Senate investigation, APF's board voted to dissolve the organization "due to irreparable economic circumstances." APF then "cease[d] to exist, effective immediately." Without support from Defendants, to whom APF could no longer be helpful, APF was no longer financially viable.

American Academy of Pain Medicine and the American Pain Society

The American Academy of Pain Medicine ("AAPM") and the American Pain Society ("APS") are professional medical societies, each of which received substantial funding from Defendants from 2009 to 2013. In 1997, AAPM issued a "consensus" statement that endorsed opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low.[164] The Chair of the committee that issued the statement, Dr. J. David Haddox, was at the time a paid speaker for Purdue. The sole consultant to the committee was Dr. Russell Portenoy, who was also a spokesperson for Purdue. The consensus statement, which also formed the foundation of the 1998 Guidelines, was published on the AAPM's website.

AAPM's corporate council includes Purdue, Depomed, Teva and other pharmaceutical companies. AAPM's past presidents include Haddox (1998), Dr. Scott Fishman ("Fishman") (2005), Dr. Perry G. Fine ("Fine") (2011) and Dr. Lynn R. Webster ("Webster") (2013), all of

whose connections to the opioid manufacturers are well-documented as set forth below.

Fishman, who also served as a KOL for Defendants, stated that he would place the organization "at the forefront" of teaching that "the risks of addiction are . . . small and can be managed."

AAPM received over $2.2 million in funding since 2009 from opioid manufacturers. AAPM maintained a corporate relations council, whose members paid $25,000 per year (on top of other funding) to participate. The benefits included allowing members to present educational programs at off-site dinner symposia in connection with AAPM's marquee event—its annual meeting held in Palm Springs, California, or other resort locations.

AAPM describes the annual event as an "exclusive venue" for offering CMEs to doctors. Membership in the corporate relations council also allows drug company executives and marketing staff to meet with AAPM executive committee members in small settings. Defendants Endo, Purdue, and Cephalon were members of the council and presented deceptive programs to doctors who attended this annual event. The conferences sponsored by AAPM heavily emphasized CME sessions on opioids—37 out of roughly 40 at one conference alone.

AAPM's staff understood that they and their industry funders were engaged in a common task. Defendants were able to influence AAPM through both their significant and regular funding and the leadership of pro-opioid KOLs within the organization.

AAPM and APS issued their own guidelines in 2009 ("2009 Guidelines"). AAPM, with the assistance, prompting, involvement, and funding of Defendants, issued the treatment guidelines discussed herein, and continued to recommend the use of opioids to treat chronic pain. Fourteen of the 21 panel members who drafted the 2009 Guidelines, including KOL Dr. Fine, received support from Defendants Janssen, Cephalon, Endo, and Purdue. Of these individuals, six

received support from Purdue, eight from Teva, nine from Janssen, and nine from Endo.

One panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and founder of the Michigan Headache & Neurological Institute, resigned from the panel because of his concerns that the Guidelines were influenced by contributions that drug companies, including Purdue, Endo, Janssen, and Teva, made to the sponsoring organizations and committee members.

Dr. Gilbert Fanciullo, now retired as a professor at Dartmouth College's Geisel School of Medicine, who also served on the AAPM/APS Guidelines panel, has since described them as "skewed" by drug companies and "biased in many important respects," including the high presumptive maximum dose, lack of suggested mandatory urine toxicology testing, and claims of a low risk of addiction.

The 2009 Guidelines have been a particularly effective channel ofdeception. They have influenced not only treating physicians, but also the scientific literature on opioids; they were reprinted in the *Journal of Pain*, have been cited hundreds of times in academic literature, were disseminated during the relevant period, and were and are available online. Treatment guidelines are especially influential with primary care physicians and family doctors to whom Defendants promoted opioids, whose lack of specialized training in pain management and opioids makes them more reliant on, and less able to evaluate, these guidelines. For that reason, the CDC has recognized that treatment guidelines can "change prescribing practices."

The 2009 Guidelines are relied upon by doctors, especially general practitioners and family doctors who have no specific training in treating chronic pain.

The Defendants widely cited and promoted the 2009 Guidelines without disclosing the lack of

evidence to support their conclusions, their involvement in the development of the Guidelines or their financial backing of the authors of these Guidelines. For example, a speaker presentation prepared by Endo in 2009 titled *The Role of Opana ER in the Management of Moderate to Severe Chronic Pain* relies on the AAPM/APS Guidelines while omitting their disclaimer regarding the lack of evidence for recommending the use of opioids for chronic pain.

Federation of State Medical Boards

The Federation of State Medical Boards ("FSMB") is a trade organization representing the various state medical boards in the United States. The state boards that comprise the FSMB membership have the power to license doctors, investigate complaints, and discipline physicians.

The FSMB finances opioid- and pain-specific programs through grants from Defendants.

Since 1998, the FSMB has been developing treatment guidelines for the use of opioids for the treatment of pain. The 1998 version, Model Guidelines for the Use of Controlled Substances for the Treatment of Pain ("1998 Guidelines") was produced "in collaboration with pharmaceutical companies." The 1998 Guidelines that the pharmaceutical companies helped author taught not that opioids could be appropriate in only limited cases after other treatments had failed, but that opioids were "essential" for treatment of chronic pain, including as a first prescription option.

A 2004 iteration of the 1998 Guidelines and the 2007 book, *Responsible Opioid Prescribing*, also made the same claims as the 1998 Guidelines. These guidelines were posted online and were available to and intended to reach physicians nationwide, including in the City of Huntington.

FSMB's 2007 publication *Responsible Opioid Prescribing* was backed largely by drug manufacturers, including Purdue, Endo and Cephalon. The publication also received support from the American Pain Foundation and the American Academy of Pain Medicine. The publication was written by Dr. Fishman, and Dr. Fine served on the Board of Advisors. In all, 163,131 copies of *Responsible Opioid Prescribing* were distributed by state medical boards (and through the boards, to practicing doctors). The FSMB website describes the book as "the leading continuing medical education (CME) activity for prescribers of opioid medications." This publication asserted that opioid therapy to relieve pain and improve function is a legitimate medical practice for acute and chronic pain of both cancer and non-cancer origins; that pain is under-treated, and that patients should not be denied opioid medications except in light of clear evidence that such medications are harmful to the patient.

The Defendants relied on the 1998 Guidelines to convey the alarming message that "under-treatment of pain" would result in official discipline, but no discipline would result if opioids were prescribed as part of an ongoing patient relationship and prescription decisions were documented. FSMB turned doctors' fear of discipline on its head: doctors, who used to believe that they would be disciplined if their patients became addicted to opioids, were taught instead that they would be punished if they failed to prescribe opioids to their patients with chronic pain.

The Alliance for Patient Access

Founded in 2006, the Alliance for Patient Access ("APA") is a self-described patient advocacy and health professional organization that styles itself as "a national network of physicians dedicated to ensuring patient access to approved therapies and appropriate clinical care."[167] It is run by Woodberry Associates LLC, a lobbying firm that was also established in 2006.[168] As

of June 2017, the APA listed 30 "Associate Members and Financial Supporters." The list includes Johnson & Johnson, Endo, Mallinckrodt, Purdue and Cephalon.

APA's board members have also directly received substantial funding from pharmaceutical companies. For instance, board vice president Dr. Srinivas Nalamachu ("Nalamachu"), who practices in Kansas, received more than $800,000 from 2013 through 2015 from pharmaceutical companies—nearly all of it from manufacturers of opioids or drugs that treat opioids' side effects, including from defendants Endo, Purdue and Cephalon. Nalamachu's clinic was raided by FBI agents in connection with an investigation of Insys and its payment of kickbacks to physicians who prescribed Subsys. Other board members include Dr. Robert A. Yapundich from North Carolina, who received $215,000 from 2013 through 2015 from pharmaceutical companies, including payments by defendants Cephalon and Mallinckrodt; Dr. Jack D. Schim from California, who received more than $240,000 between 2013 and 2015 from pharmaceutical companies, including defendants Endo, Mallinckrodt and Cephalon; Dr. Howard Hoffberg from Maryland, who received $153,000 between 2013 and 2015 from pharmaceutical companies, including defendants Endo, Purdue, Mallinckrodt and Cephalon; and Dr. Robin K. Dore from California, who received $700,000 between 2013 and 2015 from pharmaceutical companies.

Among its activities, APA issued a "white paper" titled "Prescription Pain Medication: Preserving Patient Access While Curbing Abuse." Among other things, the white paper criticizes prescription monitoring programs, purporting to express concern that they are burdensome, not user friendly, and of questionable efficacy:

Prescription monitoring programs that are difficult to use and cumbersome can place substantial burdens on physicians and their staff, ultimately leading many to stop prescribing

pain medications altogether. This forces patients to seek pain relief medications elsewhere, which may be much less convenient and familiar and may even be dangerous or illegal.

In some states, physicians who fail to consult prescription monitoring databases before prescribing pain medications for their patients are subject to fines; those who repeatedly fail to consult the databases face loss of their professional licensure. Such penalties seem excessive and may inadvertently target older physicians in rural areas who may not be facile with computers and may not have the requisite office staff. Moreover, threatening and fining physicians in an attempt to induce compliance with prescription monitoring programs represents a system based on punishment as opposed to incentives. . . .

We cannot merely assume that these programs will reduce prescription pain medication use and abuse.

The white paper also purports to express concern about policies that have been enacted in response to the prevalence of pill mills:

Although well intentioned, many of the policies designed to address this problem have made it difficult for legitimate pain management centers to operate. For instance, in some states, [pain management centers] must be owned by physicians or professional corporations, must have a Board certified medical director, may need to pay for annual inspections, and are subject to increased record keeping and reporting requirements. . . . [I]t is not even certain that the regulations are helping prevent abuses.

In addition, in an echo of earlier industry efforts to push back against what they termed "opiophobia," the white paper laments the stigma associated with prescribing and taking pain medication:

Both pain patients and physicians can face negative perceptions and outright stigma. When patients with chronic pain can't get their prescriptions for pain medication filled at a pharmacy, they may feel like they are doing something wrong—or even criminal. . . . Physicians can face similar stigma from peers. Physicians in non- pain specialty areas often look down on those who specialize in pain management—a situation fueled by the numerous regulations and fines that surround prescription pain medications.

In conclusion, the white paper states that "[p]rescription pain medications, and specifically the opioids, can provide substantial relief for people who are recovering from surgery, afflicted by chronic painful diseases, or experiencing pain associated with other conditions that does not adequately respond to over-the-counter drugs."

The APA also issues "Patient Access Champion" financial awards to members of Congress, including 50 such awards in 2015. The awards were funded by a $7.8 million donation from unnamed donors. While the awards are ostensibly given for protecting patients' access to Medicare, and are thus touted by their recipients as demonstrating a commitment to protecting the rights of senior citizens and the middle class, they appear to be given to provide cover to and reward members of Congress who have supported the APA's agenda. The APA also lobbies Congress directly. In 2015, the APA signed onto a letter supporting legislation proposed to limit the ability of the DEA to police pill mills by enforcing the "suspicious orders" provision of the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. §801 *et seq.* ("CSA" or "Controlled Substances Act"). The AAPM is also a signatory to this letter. An internal U.S. Department of Justice ("DOJ") memo stated that the proposed bill "'could actually result in increased diversion, abuse, and public health and safety consequences'" and, according to DEA chief administrative law judge John J. Mulrooney

("Mulrooney"), the law would make it "all but logically impossible" to prosecute manufacturers and distributors, like the defendants here, in the federal courts. The law passed both houses of Congress and was signed into law in 2016.

The U.S. Pain Foundation

The U.S. Pain Foundation ("USPF") was another Front Group with systematic connections and interpersonal relationships with the Defendants. The USPF was one of the largest recipients of contributions from the Defendants, collecting nearly $3 million in payments between 2012 and 2015 alone. The USPF was also a critical component of the Defendants' lobbying efforts to reduce the limits on over-prescription. The U.S. Pain Foundation advertises its ties to the Defendants, listing opioid manufacturers like Pfizer, Teva, Depomed, Endo, Purdue, McNeil *(i.e.*, Janssen), and Mallinckrodt as "Platinum," "Gold," and "Basic" corporate members. Industry Front Groups like the American Academy of Pain Management, the American Academy of Pain Medicine, the American Pain Society, and PhRMA are also members of varying levels in the USPF.

American Geriatrics Society

The American Geriatrics Society ("AGS") was another Front Group with systematic connections and interpersonal relationships with the Defendants. AGS was a large recipient of contributions from the Defendants, including Endo, Purdue and Janssen. AGS contracted with Purdue, Endo and Janssen to disseminate guidelines regarding the use of opioids for chronic pain in 2002 (*The Management of Persistent Pain in Older Persons*, hereinafter "2002 AGS Guidelines") and 2009 (Pharmacological Management of Persistent Pain in Older Persons, hereinafter "2009 AGS Guidelines"). According to news reports, AGS has received at least $344,000 in funding from opioid manufacturers since 2009. AGS's complicity in the common

purpose with the Defendants is evidenced by the fact that AGS internal discussions in August 2009 reveal that it did not want to receive-up front funding from drug companies, which would suggest drug company influence, but would instead accept commercial support to disseminate pro-opioid publications.

The 2009 AGS Guidelines recommended that "[a]ll patients with moderate to severe pain . . . should be considered for opioid therapy." The panel made "strong recommendations" in this regard despite "low quality of evidence" and concluded that the risk of addiction is manageable for patients, even with a prior history of drug abuse. These Guidelines further recommended that "the risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse." These recommendations are not supported by any study or other reliable scientific evidence. Nevertheless, they have been cited over 1,833 times in Google Scholar (which allows users to search scholarly publications that would be have been relied on by researchers and prescribers) since their 2009 publication and as recently as this year.

Representatives of the Defendants, often at informal meetings at conferences, suggested activities, lobbying efforts and publications for AGS to pursue. AGS then submitted grant proposals seeking to fund these activities and publications, knowing that drug companies would support projects conceived as a result of these communications.

Members of AGS Board of Directors were doctors who were on the Defendants' payrolls, either as consultants or speakers at medical events. As described below, many of the KOLs also served in leadership positions within the AGS.

I. **The Defendants Paid Key Opinion Leaders to Deceptively Promote Opioid Use**

To falsely promote their opioids, the Defendants paid and cultivated a select circle of doctors

who were chosen and sponsored by the Defendants for their supportive messages. As set forth below, pro-opioid doctors have been at the hub of the Defendants' well-funded, pervasive marketing scheme since its inception and were used to create the grave misperception science and legitimate medical professionals favored the wider and broader use of opioids. These doctors include Dr. Russell Portenoy and Dr. Lynn Webster, as set forth in this section, as well as Dr. Perry Fine and Dr. Scott Fishman, as set forth in further below.

Although these KOLs were funded by the Defendants, the KOLs were used extensively to present the appearance that unbiased and reliable medical research supporting the broad use of opioid therapy for chronic pain had been conducted and was being reported on by independent medical professionals.

As the Defendants' false marketing scheme picked up steam, these pro- opioid KOLs wrote, consulted on, edited, and lent their names to books and articles, and gave speeches and CMEs supportive of opioid therapy for chronic pain. They served on committees that developed treatment guidelines that strongly encouraged the use of opioids to treat chronic pain and they were placed on boards of pro-opioid advocacy groups and professional societies that develop, select, and present CMEs.

Through use of their KOLs and strategic placement of these KOLs throughout every critical distribution channel of information within the medical community, the Defendants were able to exert control of each of these modalities through which doctors receive their information.

In return for their pro-opioid advocacy, the Defendants' KOLs received money, prestige, recognition, research funding, and avenues to publish. For example, Dr. Webster has received funding from Endo, Purdue, and Cephalon. Dr. Fine has received funding from Janssen, Cephalon, Endo, and Purdue.

The Defendants carefully vetted their KOLs to ensure that they were likely to remain on-message and supportive of the Defendants' agenda. The Defendants also kept close tabs on the content of the materials published by these KOLs. And, of course, the Defendants kept these KOLs well-funded to enable them to push the Defendants' deceptive message out to the medical community.

Once the Defendants identified and funded KOLs and those KOLs began to publish "scientific" papers supporting the Defendants' false position that opioids were safe and effective for treatment of chronic pain, the Defendants poured significant funds and resources into a marketing machine that widely cited and promoted their KOLs and studies or articles by their KOLs to drive prescription of opioids for chronic pain. The Defendants cited to, distributed, and marketed these studies and articles by their KOLs as if they were independent medical literature so that it would be well-received by the medical community. By contrast, the Defendants did not support, acknowledge, or disseminate the truly independent publications of doctors critical of the use of opioid therapy.

In their promotion of the use of opioids to treat chronic pain, the Defendants' KOLs knew that their statements were false and misleading, or they recklessly disregarded the truth in doing so, but they continued to publish their misstatements to benefit themselves and the Defendants.

Dr. Russell Portenoy

In 1986, Dr. Russell Portenoy, who later became Chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York while at the same time serving as a top spokesperson for drug companies, published an article reporting that "[f]ew substantial gains in employment or social function could be attributed to the institution of opioid therapy."

Writing in 1994, Dr. Portenoy described the prevailing attitudes regarding the dangers of long-term use of opioids:

The traditional approach to chronic non-malignant pain does not accept the long-term administration of opioid drugs. This perspective has been justified by the perceived likelihood of tolerance, which would attenuate any beneficial effects over time, and the potential for side effects, worsening disability, and addiction. According to conventional thinking, the initial response to an opioid drug may appear favorable, with partial analgesia and salutary mood changes, but adverse effects inevitably occur thereafter. It is assumed that the motivation to improve function will cease as mental clouding occurs and the belief takes hold that the drug can, by itself, return the patient to a normal life. Serious management problems are anticipated, including difficulty in discontinuing a problematic therapy and the development of drug seeking behavior induced by the desire to maintain analgesic effects, avoid withdrawal, and perpetuate reinforcing psychic effects. There is an implicit assumption that little separates these outcomes from the highly aberrant behaviors associated with addiction.

(Emphasis added.) According to Dr. Portenoy, the foregoing problems could constitute "compelling reasons to reject long-term opioid administration as a therapeutic strategy in all but the most desperate cases of chronic nonmalignant pain."

Despite having taken this position on long-term opioid treatment, Dr. Portenoy ended up becoming a spokesperson for Purdue and other Defendants, promoting the use of prescription opioids and minimizing their risks. A respected leader in the field of pain treatment, Dr. Portenoy was highly influential. Dr. Andrew Kolodny, cofounder of Physicians for Responsible Opioid Prescribing, described him "lecturing around the country as a religious-like figure. The megaphone for Portenoy is Purdue, which flies in people to resorts to hear him speak. It was a

compelling message: 'Docs have been letting patients suffer; nobody really gets addicted; it's been studied." As one organizer of CME seminars who worked with Portenoy and Purdue pointed out, "had Portenoy not had Purdue's money behind him, he would have published some papers, made some speeches, and his influence would have been minor. With Purdue's millions behind him, his message, which dovetailed with their marketing plans, was hugely magnified."

Dr. Portenoy was also a critical component of the Defendants' control over their Front Groups. Specifically, Dr. Portenoy sat as a Director on the board of the APF. He was also the President of the APS.

In recent years, some of the Defendants' KOLs have conceded that many of their past claims in support of opioid use lacked evidence or support in the scientific literature. Dr. Portenoy has now admitted that he minimized the risks of opioids, and that he "gave innumerable lectures in the late 1980s and '90s about addiction that weren't true." He mused, "Did I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation? Well, against the standards of 2012, I guess I did . . ."

In a 2011 interview released by Physicians for Responsible Opioid Prescribing, Portenoy stated that his earlier work purposefully relied on evidence that was not "real" and left real evidence behind:

I gave so many lectures to primary care audiences in which the Porter and Jick article was just one piece of data that I would then cite, and I would cite six, seven, maybe ten different avenues of thought or avenues of evidence, none of which represented real evidence, and yet what I was trying to do was to create a narrative so that the primary care audience would look at this information in [total] and feel more comfortable about opioids in a way they hadn't

before. In essence this was education to destigmatize [opioids], and because the primary goal was to destigmatize, we often left evidence behind.

Several years earlier, when interviewed by journalist Barry Meier for his 2003 book, *Pain Killer*, Dr. Portenoy was more direct: "It was pseudoscience. I guess I'm going to have always to live with that one."

Dr. Lynn Webster

Another KOL, Dr. Lynn Webster, was the co-founder and Chief Medical Director of the Lifetree Clinical Research & Pain Clinic in Salt Lake City, Utah. Dr. Webster was President in 2013 and is a current board member of AAPM, a Front Group that ardently supports opioid therapy. He is a Senior Editor of *Pain Medicine*, the same journal that published Endo's special advertising supplements touting Opana ER. Dr. Webster was the author of numerous CMEs sponsored by Cephalon, Endo, and Purdue. At the same time, Dr. Webster was receiving significant funding from Defendants (including nearly $2 million from Cephalon).

Dr. Webster created and promoted the Opioid Risk Tool ("ORT"), a five question, one-minute screening tool relying on patient self-reports that purportedly allows doctors to manage the risk that their patients will become addicted to or abuse opioids. The claimed ability to pre- sort patients likely to become addicted is an important tool in giving doctors confidence to prescribe opioids long-term, and for this reason, references to screening appear in various industry-supported guidelines. Versions of Dr. Webster's ORT appear on, or are linked to, websites run by Endo, Janssen, and Purdue. In 2011, Dr. Webster presented, via webinar, a program sponsored by Purdue titled, *Managing Patient's Opioid Use: Balancing the Need and the Risk*. Dr. Webster recommended use of risk screening tools, urine testing, and patient agreements to prevent "overuse of prescriptions" and "overdose deaths." This webinar was available to and

was intended to reach doctors in Plaintiffs' County.

Dr. Webster was himself tied to numerous overdose deaths. He and the Lifetree Clinic were investigated by the DEA for overprescribing opioids after twenty patients died from overdoses. In keeping with the Defendants' promotional messages, Dr. Webster apparently believed the solution to patients' tolerance or addictive behaviors was more opioids: he prescribed staggering quantities of pills.

At an AAPM annual meeting held February 22 through 25, 2006, Cephalon sponsored a presentation by Webster and others titled, "Open-label study of fentanyl effervescent buccal tablets in patients with chronic pain and breakthrough pain: Interim safety results." The presentation's agenda description states: "Most patients with chronic pain experience episodes of breakthrough pain, yet no currently available pharmacologic agent is ideal for its treatment." The presentation purports to cover a study analyzing the safety of a new form of fentanyl buccal tablets in the chronic pain setting and promises to show the "[i]nterim results of this study suggest that FEBT is safe and well-tolerated in patients with chronic pain and BTP." This CME effectively amounted to off-label promotion of Cephalon's opioids—the only drugs in this category—for chronic pain, even though they were approved only for cancer pain.

Cephalon sponsored a CME written by Dr. Webster, *Optimizing Opioid Treatment for Breakthrough Pain*, offered by Medscape, LLC from September 28, 2007 through December 15, 2008. The CME taught that non-opioid analgesics and combination opioids containing non-opioids such as aspirin and acetaminophen are less effective at treating breakthrough pain because of dose limitations on the non-opioid component.

Dr. Perry Fine

Dr. Perry Fine's ties to the Defendants are well documented. He has authored articles and testified in court cases and before state and federal committees, and he, too, has argued against legislation restricting high-dose opioid prescription for non-cancer patients. He has served on Purdue's advisory board, provided medical legal consulting for Janssen, and participated in CME activities for Endo, along with serving in these capacities for several other drug companies. He co-chaired the APS/AAPM Opioid Guideline Panel, served as treasurer of the AAPM from 2007 to 2010 and as president of that group from 2011 to 2013, and was on the board of directors of APF.

Multiple videos feature Fine delivering educational talks about prescription opioids. He even testified at trial that the 1,500 pills a month prescribed to celebrity Anna Nicole Smith for pain did not make her an addict before her death.

He has also acknowledged having failed to disclose numerous conflicts of interest. For example, Dr. Fine failed to fully disclose payments received as required by his employer, the University of Utah—telling the university that he had received under $5,000 in 2010 from Johnson & Johnson for providing "educational" services, but Johnson & Johnson's website states that the company paid him $32,017 for consulting, promotional talks, meals and travel that year.

Dr. Fine and Dr. Portenoy co-wrote *A Clinical Guide to Opioid Analgesia*, in which they downplayed the risks of opioid treatment, such as respiratory depression and addiction:

At clinically appropriate doses, . . . respiratory rate typically does not decline. Tolerance to the respiratory effects usually develops quickly, and doses can be steadily increased without risk.

Overall, the literature provides evidence that the outcomes of drug abuse and addiction are rare

among patients who receive opioids for a short period (ie, for acute pain) and among those with no history of abuse who receive long-term therapy for medical indications.

In November 2010, Dr. Fine and others published an article presenting the results of another Cephalon-sponsored study titled "Long-Term Safety and Tolerability of Fentanyl Buccal Tablet for the Treatment of Breakthrough Pain in Opioid-Tolerant Patients with Chronic Pain: An 18-Month Study."[193] In that article, Dr. Fine explained that the 18-month "open-label" study "assessed the safety and tolerability of FBT [Fentora] for the [long-term] treatment of BTP in a large cohort . . . of opioid-tolerant patients receiving around-the-clock . . . opioids for noncancer pain." The article acknowledged that: (a) "[t]here has been a steady increase in the use of opioids for the management of chronic noncancer pain over the past two decades"; (b) the "widespread acceptance" had led to the publishing of practice guidelines "to provide evidence- and consensus-based recommendations for the optimal use of opioids in the management of chronic pain"; and (c) those guidelines lacked "data assessing the long-term benefits and harms of opioid therapy for chronic pain."

The article concluded: "[T]he safety and tolerability profile of FBT in this study was generally typical of a potent opioid. The [adverse events] observed were, in most cases, predictable, manageable, and tolerable." They also conclude that the number of abuse-related events was "small."

Multiple videos feature Dr. Fine delivering educational talks about the drugs. In one video from 2011 titled "Optimizing Opioid Therapy," he sets forth a "Guideline for Chronic Opioid Therapy" discussing "opioid rotation" (switching from one opioid to another) not only for cancer patients, but for non-cancer patients, and suggests it may take four or five switches over a person's "lifetime" to manage pain. He states the "goal is to improve effectiveness which is

different from efficacy and safety." Rather, for chronic pain patients, effectiveness "is a balance of therapeutic good and adverse events *over the course of years*." The entire program assumes that opioids are appropriate treatment over a "protracted period of time" and even over a patient's entire "lifetime." He even suggests that opioids can be used to treat *sleep apnea*. He further states that the associated risks of addiction and abuse can be managed by doctors and evaluated with "tools," but leaves that for "a whole other lecture."

Dr. Scott Fishman

Dr. Scott Fishman is a physician whose ties to the opioid drug industry are legion. He has served as an APF board member and as president of the AAPM, and has participated yearly in numerous CME activities for which he received "market rate honoraria." As discussed below, he has authored publications, including the seminal guides on opioid prescribing, which were funded by the Defendants. He has also worked to oppose legislation requiring doctors and others to consult pain specialists before prescribing high doses of opioids to non-cancer patients. He has himself acknowledged his failure to disclose all potential conflicts of interest in a letter in the *Journal of the American Medical Association* titled "Incomplete Financial Disclosures in a Letter on Reducing Opioid Abuse and Diversion."

In 2007, Dr. Fishman authored a physician's guide on the use of opioids to treat chronic pain titled *Responsible Opioid Prescribing*, which promoted the notion that long-term opioid treatment was a viable and safe option for treating chronic pain.

In 2012, Dr. Fishman updated the guide and continued emphasizing the "catastrophic" "under-treatment" of pain and the "crisis" such under-treatment created:

Given the magnitude of the problems related to opioid analgesics, it can be tempting to resort to

draconian solutions: clinicians may simply stop prescribing opioids, or legislation intended to improve pharmacovigilance may inadvertently curtail patient access to care. As we work to reduce diversion and misuse of prescription opioids, it's critical to remember that the problem of unrelieved pain remains as urgent as ever.

The updated guide still assures that "[o]pioid therapy to relieve pain and improve function is legitimate medical practice for acute and chronic pain of both cancer and noncancer origins."

In another guide by Dr. Fishman, he continues to downplay the risk of addiction: "I believe clinicians must be very careful with the label 'addict.' I draw a distinction between a 'chemical coper' and an addict." The guide also continues to present symptoms of addiction as symptoms of "pseudoaddiction."

J. The Defendants Disseminated Their Misrepresentations Through Continuing Medical Education Programs

Now that the Defendants had both a group of physician promoters and had built a false body of "literature," Defendants needed to make sure their false marketing message was widely distributed.

One way the Defendants aggressively distributed their false message was through thousands of Continuing Medical Education courses ("CMEs").

A CME is a professional education program provided to doctors. Doctors are required to attend a certain number and, often, type of CME programs each year as a condition of their licensure. These programs are delivered in person, often in connection with professional organizations' conferences, and online, or through written publications. Doctors rely on CMEs not only to satisfy licensing requirements, but also to get information on new developments in medicine or

to deepen their knowledge in specific areas of practice. Because CMEs typically are taught by KOLs who are highly respected in their fields, and are thought to reflect these physicians' medical expertise, they can be especially influential with doctors.

The countless doctors and other health care professionals who participate in accredited CMEs constitute an enormously important audience for opioid reeducation. As one target, Defendants aimed to reach general practitioners, whose broad area of practice and lack of expertise and specialized training in pain management made them particularly dependent upon CMEs and, as a result, especially susceptible to the Defendants' deceptions.

The Defendants sponsored CMEs that were delivered thousands of times, promoting opioid therapy and supporting and disseminating the deceptive and biased messages described in this Complaint. These CMEs, while often generically titled to relate to the treatment of chronic pain, focus on opioids to the exclusion of alternative treatments, inflate the benefits of opioids, and frequently omit or downplay their risks and adverse effects.

Cephalon sponsored numerous CME programs, which were made widely available through organizations like Medscape, LLC ("Medscape") and which disseminated false and misleading information to physicians across the country.

Another Cephalon-sponsored CME presentation titled *Breakthrough Pain: Treatment Rationale with Opioids* was available on Medscape starting September 16, 2003 and was given by a self-professed pain management doctor who treated "previously operated back, complex pain syndromes, the neuropathies, and interstitial cystitis." He describes the pain process as a non-time-dependent continuum that requires a balanced analgesia approach using "targeted pharmacotherapeutics to affect multiple points in the pain-signaling pathway." The doctor lists fentanyl as one of the most effective opioids available for treating breakthrough pain,

describing its use as an expected and normal part of the pain management process. Nowhere in the CME is cancer or cancer-related pain even mentioned, despite FDA restrictions that fentanyl use be limited to cancer-related pain.

Teva paid to have a CME it sponsored, *Opioid-Based Management of Persistent and Breakthrough Pain*, published in a supplement of Pain Medicine News in 2009. The CME instructed doctors that "clinically, broad classification of pain syndromes as either cancer- or noncancer-related has limited utility" and recommended Actiq and Fentora for patients with chronic pain. The CME is still available online.

Responsible Opioid Prescribing was sponsored by Purdue, Endo and Teva. The FSMB website described it as the "leading continuing medical education (CME) activity for prescribers of opioid medications." Endo sales representatives distributed copies of *Responsible Opioid Prescribing* with a special introductory letter from Dr. Scott Fishman.

In all, more than 163,000 copies of *Responsible Opioid Prescribing* were distributed nationally.

The American Medical Association ("AMA") recognized the impropriety that pharmaceutical company-funded CMEs creates, stating that support from drug companies with a financial interest in the content being promoted "creates conditions in which external interests could influence the availability and/or content" of the programs and urges that "[w]hen possible, CME[s] should be provided without such support or the participation of individuals who have financial interests in the education subject matter."

Physicians attended or reviewed CMEs sponsored by the Defendants during the relevant time period and were misled by them.

By sponsoring CME programs put on by Front Groups like APF, AAPM, and others, the

Defendants could expect instructors to deliver messages favorable to them, as these organizations were dependent on the Defendants for other projects. The sponsoring organizations honored this principle by hiring pro-opioid KOLs to give talks that supported opioid therapy. Defendant-driven content in these CMEs had a direct and immediate effect on prescribers' views on opioids. Producers of CMEs and the Defendants both measured the effects of CMEs on prescribers' views on opioids and their absorption of specific messages, confirming the strategic marketing purpose in supporting them.

K. The Defendants Used "Branded" Advertising to Promote their Products to Doctors and Consumers

The Defendants engaged in widespread advertising campaigns touting the benefits of their branded drugs. The Defendants published print advertisements in a broad array of medical journals, ranging from those aimed at specialists, such as the *Journal of Pain* and *Clinical Journal of Pain*, to journals with wider medical audiences, such as the *Journal of the American Medical Association*. The Defendants collectively spent more than $14 million on the medical journal advertising of opioids in 2011, nearly triple what they spent in 2001. The 2011 total includes $8.3 million by Purdue, $4.9 million by Janssen, and $1.1 million by Endo.

The Defendants also targeted consumers in their advertising. They knew that physicians are more likely to prescribe a drug if a patient specifically requests it. They also knew that this willingness to acquiesce to such patient requests holds true even for opioids and for conditions for which they are not approved. Endo's research, for example, also found that such communications resulted in greater patient "brand loyalty," with longer durations of Opana ER therapy and fewer discontinuations. The Defendants thus increasingly took their opioid sales campaigns directly to consumers, including through patient-focused "education and support"

materials in the form of pamphlets, videos, or other publications that patients could view in their physician's office.

L. The Defendants Used "Unbranded" Advertising to Promote Opioid Use for Chronic Pain Without FDA Review

The Defendants also aggressively promoted opioids through "unbranded advertising" to generally tout the benefits of opioids without specifically naming a particular brand-name opioid drug. Instead, unbranded advertising is usually framed as "disease awareness"—encouraging consumers to "talk to your doctor" about a certain health condition without promoting a specific product and, therefore, without providing balanced disclosures about the product's limits and risks. In contrast, a pharmaceutical company's "branded" advertisement that identifies a specific medication and its indication (i.e., the condition which the drug is approved to treat) must also include possible side effects and contraindications—what the FDA Guidance on pharmaceutical advertising refers to as "fair balance." Branded advertising is also subject to FDA review for consistency with the drug's FDA-approved label. Through unbranded materials, the Defendants expanded the overall acceptance of and demand for opioid therapy without the restrictions imposed by regulations on branded advertising.

Many of the Defendants utilized unbranded websites to promote opioid use without promoting a specific branded drug, such as Purdue's pain-management website, *www.inthefaceofpain.com*. The website contained testimonials from several dozen "advocates," including health care providers, urging more pain treatment. The website presented the advocates as neutral and unbiased, but an investigation by the New York Attorney General later revealed that Purdue paid the advocates hundreds of thousands of dollars.

M. The Defendants Funded, Edited and Distributed Publications That Supported

Their Misrepresentations

The Defendants created a body of false, misleading, and unsupported medical and popular literature about opioids that (a) understated the risks and overstated the benefits of long-term use; (b) appeared to be the result of independent, objective research; and (c) was likely to shape the perceptions of prescribers, patients, and payors. This literature served marketing goals, rather than scientific standards, and was intended to persuade doctors and consumers that the benefits of long-term opioid use outweighed the risks.

To accomplish their goal, the Defendants—sometimes through third- party consultants and/or Front Groups—commissioned, edited, and arranged for the placement of favorable articles in academic journals.

The Defendants' plans for these materials did not originate in the departments with the organizations that were responsible for research, development, or any other area that would have specialized knowledge about the drugs and their effects on patients; rather, they originated in the Defendants' marketing departments.

The Defendants made sure that favorable articles were disseminated and cited widely in the medical literature, even when the Defendants knew that the articles distorted the significance or meaning of the underlying study, as with the Porter & Jick letter. The Defendants also frequently relied on unpublished data or posters, neither of which are subject to peer review, but were presented as valid scientific evidence.

The Defendants published or commissioned deceptive review articles, letters to the editor, commentaries, case-study reports, and newsletters aimed at discrediting or suppressing negative information that contradicted their claims or raised concerns about opioid therapy.

For example, in 2007 Cephalon sponsored the publication of an article titled "Impact of Breakthrough Pain on Quality of Life in Patients with Chronic, Noncancer Pain: Patient Perceptions and Effect of Treatment with Oral Transmucosal Fentanyl Citrate," published in the nationally circulated journal *Pain Medicine*, to support its effort to expand the use of its branded fentanyl products. The article's authors (including Dr. Lynn Webster, discussed above) stated that the "OTFC [fentanyl] has been shown to relieve BTP more rapidly than conventional oral, normal- release, or 'short acting' opioids" and that "[t]he purpose of [the] study was to provide a qualitative evaluation of the effect of BTP on the [quality of life] of noncancer pain patients." The number- one-diagnosed cause of chronic pain in the patients studied was back pain (44%), followed by musculoskeletal pain (12%) and head pain (7%). The article cites Portenoy and recommends fentanyl for non-cancer BTP patients:

In summary, BTP appears to be a clinically important condition in patients with chronic noncancer pain and is associated with an adverse impact on QoL. This qualitative study on the negative impact of BTP and the potential benefits of BTP-specific therapy suggests several domains that may be helpful in developing BTP- specific, QoL assessment tools.

The Defendants Used Detailing to Directly Disseminate Their Misrepresentations to Prescribers

The Defendants' sales representatives executed carefully crafted marketing tactics, developed at the highest rungs of their corporate ladders, to reach targeted doctors with centrally orchestrated messages. The Defendants' sales representatives also distributed third-party marketing material to their target audience that was deceptive.

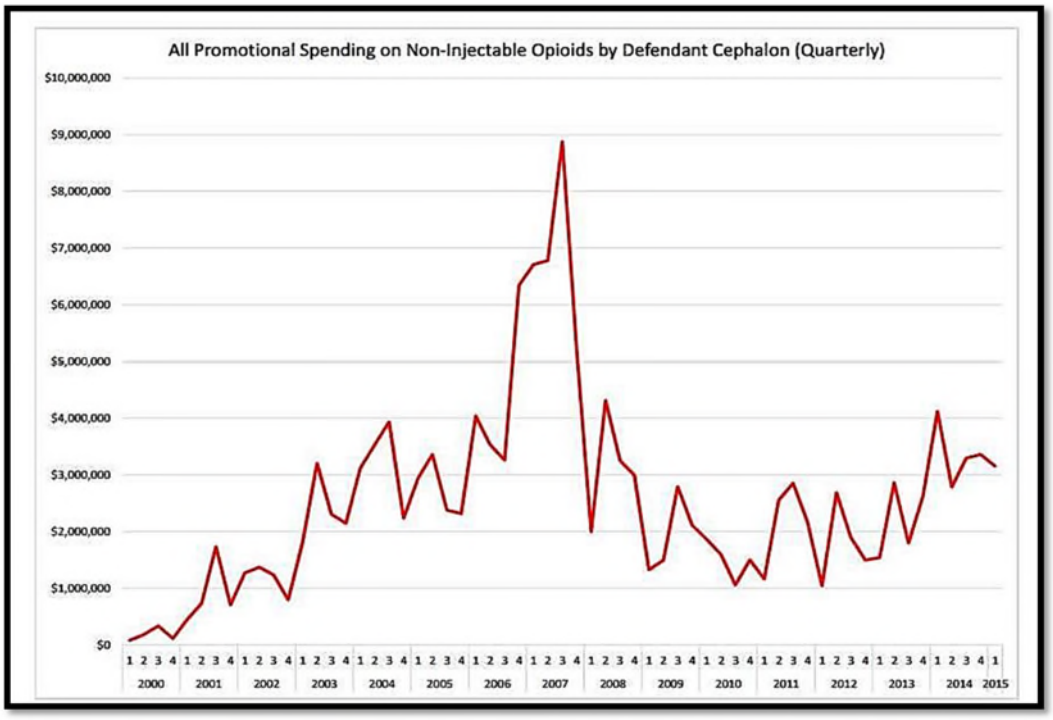
Each Defendant promoted opioids through sales representatives (also called "detailers") and, upon information and belief, small group speaker programs to reach out to individual prescribers. By establishing close relationships with doctors, the Defendants were able to

disseminate their misrepresentations in targeted, one-on-one settings that allowed them to promote their opioids and to allay individual prescribers' concerns about prescribing opioids for chronic pain.

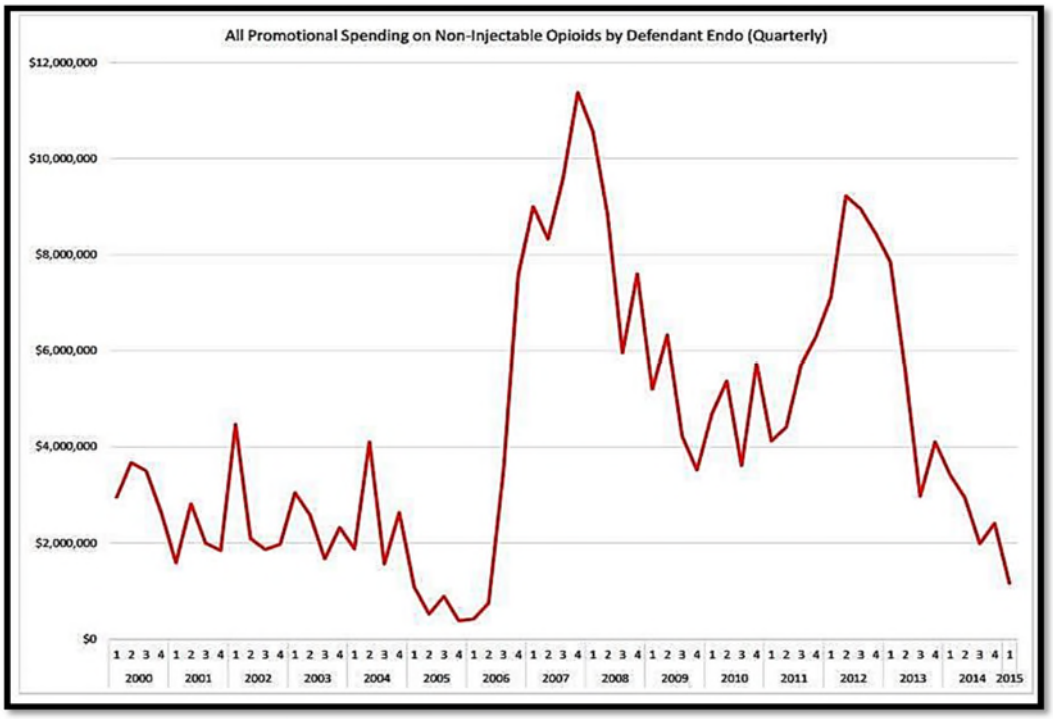
In accordance with common industry practice, the Defendants purchase and closely analyze prescription sales data from IMS Health (now IQVIA), a healthcare data collection, management and analytics corporation. This data allows them to track precisely the rates of initial and renewal prescribing by individual doctors, which allows them to target and tailor their appeals. Sales representatives visited hundreds of thousands of doctors and disseminated the misinformation and materials described above.

Defendants devoted and continue to devote massive resources to direct sales contacts with doctors. In 2014 alone, Defendants spent $166 million on detailing branded opioids to doctors. This amount is twice as much as Defendants spent on detailing in 2000. The amount includes $108 million spent by Purdue, $34 million by Janssen, $13 million by Teva, and $10 million by Endo.

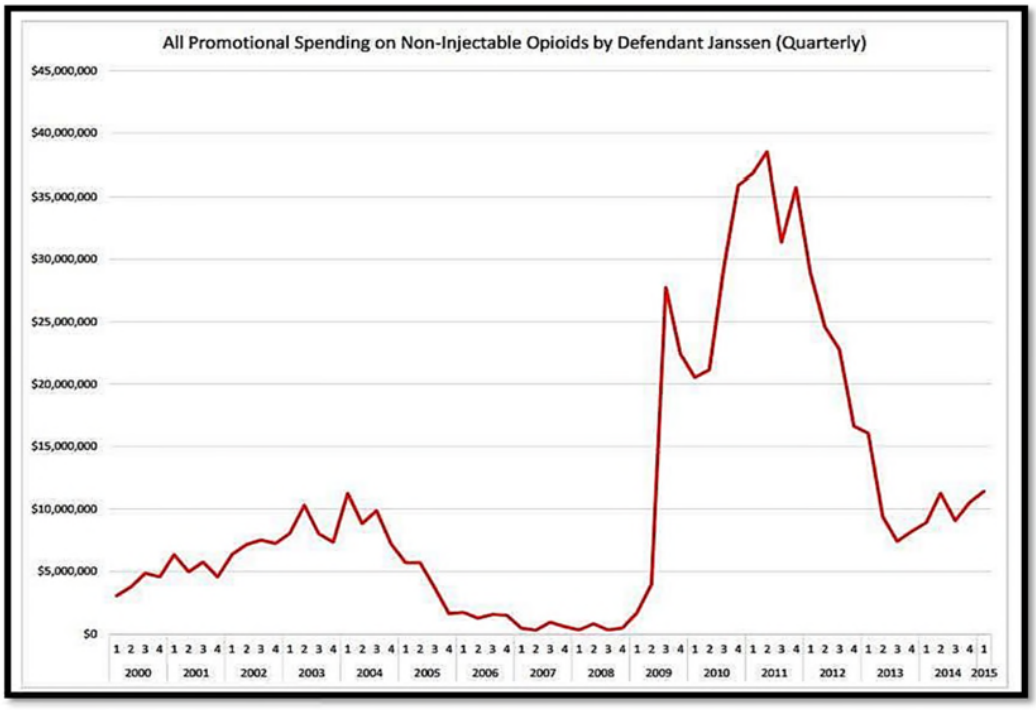
Cephalon's quarterly spending steadily climbed from below $1 million in 2000 to more than $3 million in 2014 (and more than $13 million for the year), with a peak, coinciding with the launch of Fentora, of more than $27 million in 2007, as shown below:



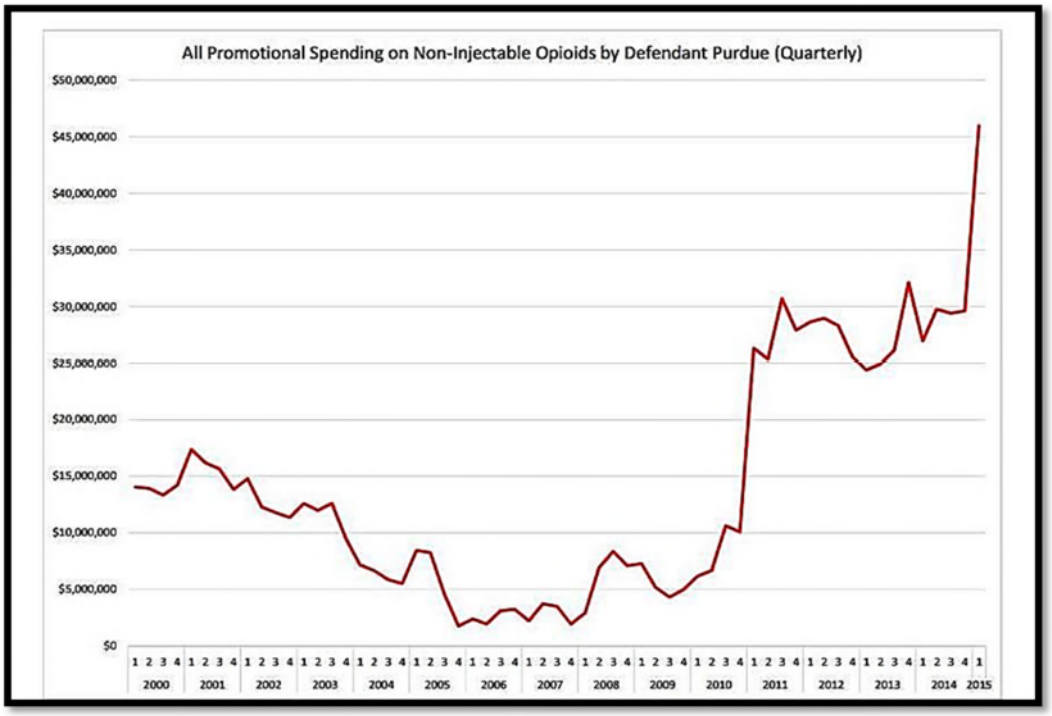
Endo's quarterly spending went from the $2 million to $4 million range in 2000- 2004 to more than $10 million following the launch of Opana ER in mid-2006 (and more than $38 million for the year in 2007) and more than $8 million coinciding with the launch of a reformulated version in 2012 (and nearly $34 million for the year):



Janssen's quarterly spending dramatically rose from less than $5 million in 2000 to more than $30 million in 2011, coinciding with the launch of Nucynta ER (with yearly spending at $142 million for 2011), as shown below:



Purdue's quarterly spending notably decreased from 2000 to 2007, as Purdue came under investigation by the Department of Justice, but then spiked to above $25 million in 2011 (for a total of $110 million that year), and continues to rise, as shown below:



For its opioid, Actiq, Cephalon also engaged in direct marketing in direct contravention of the FDA's strict instructions that Actiq be prescribed only to terminal cancer patients and by oncologists and pain management doctors experienced in treating cancer pain.

Thousands of prescribers attended Cephalon speaking programs. Cephalon tracked the impact that these programs had on prescribing in the three months following the event and concluded that doctors' prescribing of Fentora often increased.

N. Defendants Used Speakers' Bureaus and Programs to Spread Their Deceptive Messages

In addition to making sales calls, Marketers' detailers also identified doctors to serve, for

payment, on their speakers' bureaus and to attend programs with speakers and meals paid for by the Defendants. These speaker programs and associated speaker trainings serve three purposes: they provide an incentive to doctors to prescribe, or increase their prescriptions of, a particular drug; to qualify to be selected a forum in which to further market to the speaker himself or herself; and an opportunity to market to the speaker's peers. The Defendants grade their speakers, and future opportunities are based on speaking performance, post-program sales, and product usage. Purdue, Janssen, Endo, Cephalon, and Mallinckrodt each made thousands of payments to physicians nationwide, for activities including participating on speakers' bureaus, providing consulting services, and other services.

VI. CLASS ACTION ALLEGATIONS

Plaintiffs bring this action on behalf of themselves and as a nationwide class action under Rule 23(b)(3) of the Federal Rules of Civil Procedure seeking injunctive damages, pre-judgment and post-judgment interest, and declaratory relief, as well as costs of suit and attorneys' fees, for violations of the Anti-trust Act and/or Consumer Act(s) of the following jurisdictions:

All persons residing in the following states of Alabama, Arizona, Arkansas, California, District of Columbia, Florida, Hawaii, Illinois, Iowa, Kansas, Maine, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Carolina, North Dakota, Oregon, South Dakota, Tennessee, Utah, Vermont, West Virginia and Wisconsin that, during the period from January 2008 until the present (the "Class Period"), directly or indirectly purchased prescription opioid medication for their own use and not for resale.

Plaintiffs bring this action on behalf of themselves and as a class action under Rule 23(b)(3) of the Federal Rules of Civil Procedure seeking damages, costs and attorneys fees, including

interest and punitive damages, on behalf of themselves and class members residing in states listed above that provide a damages remedy for direct/indirect purchasers.

While Plaintiffs do not know the exact number of the members of the Classes, Plaintiffs believe there are at least thousands of persons and entities.

Common questions of law and fact exist as to all members of the Classes. This is particularly true given the nature of Defendants' conspiracy, which was applicable to all of the members of the Classes, thereby making appropriate relief with respect to the Classes as a whole. Such questions of law and fact common to the Classes include, but are not limited to:

Whether Defendants agreed to restrain competition in the market for opioid medication;

Whether Defendants exercised monopoly power in the market for opioid medication;

Whether Defendants conspired to monopolize the market for opioid medication;

Whether Defendants had a dangerous probability of achieving monopoly power in the market for opioid medication;

Whether Defendants' conduct raised the price of opioid medication above what it otherwise would have been absent their conduct;

Whether Defendants' conduct raised the price of opioid medication above what it otherwise would have been absent their conduct;

Whether Defendants' practices caused injury to the business or property of Plaintiffs and the members of the Classes; and

The appropriate class-wide measure of damages for the Damages Class.

Plaintiffs' claims are typical of the claims of the Classes, and Plaintiffs will fairly and

adequately protect the interests of the Classes. Plaintiffs and all members of the Classes are similarly affected by Defendants' wrongful conduct in that they paid artificially inflated prices for opioid medication during the Class Period.

Plaintiffs' claims arise out of the same common course of conduct giving rise to the claims of the other members of the Classes. Plaintiffs' interests are coincident with, and not antagonistic to, those of the other members of the Classes. Plaintiffs are represented by counsel who are competent and experienced in the prosecution of antitrust, consumer protection and class action litigation.

The questions of law and fact common to the members of the Classes predominate over any questions affecting only individual members, including legal and factual issues relating to liability and damages.

Class action treatment is a superior method for the fair and efficient adjudication of the controversy, in that, among other things, such treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently and without the unnecessary duplication of evidence, effort and expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities with a method for obtaining redress

for claims that it might not be practicable to pursue individually, substantially outweigh any difficulties that may arise in management of this class action.

A. COUNT I- Violation Of State Antitrust Laws (On Behalf of Plaintiffs and the Damages Class)

Plaintiffs incorporate and reallege, as though fully set forth herein, each of the paragraphs set

forth above.

During the Class Period, Defendants and their co-conspirators engaged in a continuing contract, combination, or conspiracy with respect to the sale of opioid medication in unreasonable restraint of trade and in violation of the following state statues.

1) Alabama: By reason of the foregoing, Defendants have violated Alabama Code § 6-5-60. Plaintiffs on behalf of the Damages Class allege as follows:

Defendants' combination or conspiracy had the following effects: (1) price competition for opioid medication was restrained, suppressed, and eliminated throughout Alabama; (2) prices for opioid medication were raised, fixed, maintained, and stabilized at artificially high levels throughout Alabama; (3) Plaintiffs and members of the Damages Class were deprived of free and open competition; and (4) Plaintiffs and members of the Damages Class paid supra-competitive, artificially-inflated prices for opioid medication.

During the Class Period, Defendants' illegal conduct substantially affected Alabama commerce.

As a direct and proximate result of Defendants' unlawful conduct, Plaintiffs and members of the Damages Class have been injured in their business and property and are threatened with further injury.

By reason of the foregoing, Defendants entered into agreements in restraint of trade in violation of Alabama Code § 6-5-60. Accordingly, Plaintiffs and members of the Damages Class seek all forms of relief available under Alabama Code § 6-5-60.

2) Arizona: By reason of the foregoing, Defendants have violated Arizona Revised Statutes, §§ 44-1401, *et seq*. Plaintiffs on behalf of the Damages Class allege as follows:

Defendants' combination or conspiracy had the following effects: (1) price competition for medication was restrained, suppressed, and eliminated throughout Arizona; (2) prices for opioid medication were raised, fixed, maintained, and stabilized at artificially high levels throughout Arizona; (3) Plaintiffs and members of the Damages Class were deprived of free and open competition; and (4) Plaintiffs and members of the Damages Class paid supra-competitive, artificially-inflated prices for opioid medication.

During the Class Period, Defendants' illegal conduct substantially affected Arizona commerce.

As a direct and proximate result of Defendants' unlawful conduct, Plaintiffs and members of the Damages Class have been injured in their business and property and are threatened with further injury.

By reason of the foregoing, Defendants entered into agreements in restraint of trade in violation of Arizona Revised Statutes, §§ 44-1401, *et seq*. Accordingly, Plaintiffs and members of the Damages Class seek all forms of relief available under Arizona Revised Statutes, §§ 44-1401, *et seq*.

3) California: By reason of the foregoing, Defendants have violated California

Business and Professions Code, §§ 16700, *et seq*. Plaintiffs on behalf of the Damages Class allege as follows:

Defendants and their co-conspirators entered into and engaged in a continuing unlawful trust in restraint of the trade and commerce described above in violation California Business and Professions Code § 16720. Defendants, and each of them, have acted in violation of § 16720 to fix, raise, stabilize, and maintain prices of opioid medication at supra-competitive levels.

The aforesaid violations of California Business and Professions Code § 16720 consisted,

without limitation, of a continuing unlawful trust and concert of action among the Defendants and their co-conspirators, the substantial terms of which were to fix, raise, maintain, and stabilize the prices of opioid medication.

For the purpose of forming and effectuating the unlawful trust, the Defendants and their co-conspirators have done those things which they combined and conspired to do, including but not in any way limited to the acts, practices and course of conduct set forth above and fixing, raising, stabilizing, and pegging the price of opioid medication.

The combination and conspiracy alleged herein has had, *inter alia*, the following effects: (1) price competition in the sale of opioid medication has been restrained, suppressed, and/or eliminated in the State of California; (2) prices for opioid medication have been fixed, raised, stabilized, and pegged at artificially high, noncompetitive levels in the State of California; and (3) those who purchased opioid medication directly or indirectly from Defendants and their co-conspirators have been deprived of the benefit of free and open competition.

As a direct and proximate result of Defendants' unlawful conduct, Plaintiffs and the members of the Damages Class have been injured in their business and property in that they paid more for opioid medication than they otherwise would have paid in the absence of Defendants' unlawful conduct. As a result of Defendants' violation of California Business and Professions Code § 16720, Plaintiffs and the Damages Class seek treble damages and their cost of suit, including a reasonable attorney's fee, pursuant to California Business and Professions Code § 16750(a).

4) District of Columbia: By reason of the foregoing, Defendants have violated District of Columbia Code, §§ 28-4501, *et seq.* Plaintiffs on behalf of the Damages Class allege

as follows:

Defendants' combination or conspiracy had the following effects: (1) price competition for opioid medication was restrained, suppressed, and eliminated throughout the District of Columbia; (2) prices for opioid medication were raised, fixed, maintained, and stabilized at artificially high levels throughout the District of Columbia; (3) Plaintiffs and members of the Damages Class, including those who resided in the District of Columbia and/or purchased opioid medication that was shipped by Defendants or their co-conspirators, were deprived of free and open competition, including in the District of Columbia; and (4) Plaintiffs and members of the Damages Class, including those who resided in the District of Columbia and/or purchased opioid medication that was shipped by Defendants or their co-conspirators, paid supra-competitive, artificially-inflated prices for opioid medication, including in the District of Columbia.

During the Class Period, Defendants' illegal conduct substantially affected District of Columbia commerce.

As a direct and proximate result of Defendants' unlawful conduct, Plaintiffs and members of the Damages Class have been injured in their business and property and are threatened with further injury.

By reason of the foregoing, Defendants entered into agreements in restraint of trade in violation of District of Columbia Code, §§ 28-4501, *et seq*. Accordingly, Plaintiffs and members of the Damages Class seek all forms of relief available under District of Columbia Code, §§ 28-4501, *et seq*.

5) Hawaii: By reason of the foregoing, Defendants have violated Hawaii Revised

Statutes, §§ 480-1, *et seq*. Plaintiffs on behalf of the Damages Class allege as follows:

Defendants' combination or conspiracy had the following effects: (1) price competition for opioid medication was restrained, suppressed, and eliminated throughout Hawaii; (2) prices for opioid medication were raised, fixed, maintained, and stabilized at artificially high levels throughout Hawaii; (3) Plaintiffs and members of the Damages Class were deprived of free and open competition; and (4) Plaintiffs and members of the Damages Class paid supra-competitive, artificially-inflated prices for opioid medication.

During the Class Period, Defendants' illegal conduct substantially affected Hawaii commerce.

As a direct and proximate result of Defendants' unlawful conduct, Plaintiffs and members of the Damages Class have been injured in their business and property and are threatened with further injury.

By reason of the foregoing, Defendants entered into agreements in restraint of trade in violation of Hawaii Revised Statutes, §§ 480-1, *et seq*. Accordingly, Plaintiffs and members of the Damages Class seek all forms of relief available under Hawaii Revised Statutes, §§ 480-1, *et seq*.

6) Illinois: By reason of the foregoing, Defendants have violated the Illinois

Antitrust Act, 740 Illinois Compiled Statutes 10/1, *et seq*. Plaintiffs on behalf of the Damages Class allege as follows:

Defendants' combination or conspiracy had the following effects: (1) price competition for opioid medication was restrained, suppressed, and eliminated throughout Illinois; (2) prices for generic opioid medication were raised, fixed, maintained, and stabilized at artificially high levels throughout Illinois; (3) Plaintiffs and members of the Damages Class were deprived of

free and open competition; and (4) Plaintiffs and members of the Damages Class paid supra-competitive, artificially-inflated prices for opioid medication.

During the Class Period, Defendants' illegal conduct substantially affected Illinois commerce.

As a direct and proximate result of Defendants' unlawful conduct, Plaintiffs and members of the Damages Class have been injured in their business and property and are threatened with further injury.

By reason of the foregoing, Defendants entered into agreements in restraint of trade in violation of the Illinois Antitrust Act, 740 Illinois Compiled Statutes 10/1, *et seq*. Accordingly, Plaintiffs and members of the Damages Class seek all forms of relief available under the Illinois Antitrust Act, 740 Illinois Compiled Statutes 10/1, *et seq*.

7) Iowa: By reason of the foregoing, Defendants have violated Iowa Code, §§ 553.1, *et seq*. Plaintiffs on behalf of the Damages Class allege as follows:

Defendants' combination or conspiracy had the following effects: (1) price competition for opioid medication was restrained, suppressed, and eliminated throughout Iowa; (2) prices for opioid medication were raised, fixed, maintained, and stabilized at artificially high levels throughout Iowa; (3) Plaintiffs and members of the Damages Class were deprived of free and open competition; and (4) Plaintiffs and members of the Damages Class paid supra-competitive, artificially-inflated prices for opioid medication.

During the Class Period, Defendants' illegal conduct substantially affected Iowa commerce.

As a direct and proximate result of Defendants' unlawful conduct, Plaintiffs and members of the Damages Class have been injured in their business and property and are threatened with further injury.

By reason of the foregoing, Defendants entered into agreements in restraint of trade in violation of Iowa Code, §§ 553.1, *et seq*. Accordingly, Plaintiffs and members of the Damages Class seek all forms of relief available under Iowa Code, §§ 553.1, *et seq*.

8) Kansas: By reason of the foregoing, Defendants have violated Kansas Statutes, §§ 50-101, *et seq*. Plaintiffs on behalf of the Damages Class allege as follows:

Defendants' combination or conspiracy had the following effects: (1) price competition for opioid medication was restrained, suppressed, and eliminated throughout Kansas; (2) prices for opioid medication were raised, fixed, maintained, and stabilized at artificially high levels throughout Kansas; (3) Plaintiffs and members of the Damages Class were deprived of free and open competition; and (4) Plaintiffs and members of the Damages Class paid supra-competitive, artificially-inflated prices for opioid medication.

During the Class Period, Defendants' illegal conduct substantially affected Kansas commerce.

As a direct and proximate result of Defendants' unlawful conduct, Plaintiffs and members of the Damages Class have been injured in their business and property and are threatened with further injury.

By reason of the foregoing, Defendants entered into agreements in restraint of trade in violation of Kansas Statutes, §§ 50-101, *et seq*. Accordingly, Plaintiffs and members of the Damages Class seek all forms of relief available under Kansas Statutes, §§ 50- 101, *et seq*.

9) Maine: By reason of the foregoing, Defendants have violated Maine Revised Statutes, 10 M.R.S.A. §§ 1101, *et seq*. Plaintiffs on behalf of the Damages Class allege as follows:

Defendants' combination or conspiracy had the following effects: (1) price competition for

opioid medication was restrained, suppressed, and eliminated throughout Maine; (2) prices for opioid medication were raised, fixed, maintained, and stabilized at artificially high levels throughout Maine; (3) Plaintiffs and members of the Damages Class were deprived of free and open competition; and (4) Plaintiffs and members of the Damages Class paid supra-competitive, artificially-inflated prices for opioid medication.

During the Class Period, Defendants' illegal conduct substantially affected Maine commerce.

As a direct and proximate result of Defendants' unlawful conduct, Plaintiffs and members of the Damages Class have been injured in their business and property and are threatened with further injury.

By reason of the foregoing, Defendants entered into agreements in restraint of trade in violation of Maine Revised Statutes, 10 M.R.S.A. §§ 1101, *et seq*. Accordingly, Plaintiffs and members of the Damages Class seek all forms of relief available under Maine Revised Statutes, 10 M.R.S.A. §§ 1101, *et seq*.

10) Michigan: By reason of the foregoing, Defendants have violated Michigan Compiled Laws, §§ 445.771, *et seq*. Plaintiffs on behalf of the Damages Class allege as follows:

Defendants' combination or conspiracy had the following effects: (1) price competition for opioid medication was restrained, suppressed, and eliminated throughout Michigan; (2) prices for opioid medication were raised, fixed, maintained, and stabilized at artificially high levels throughout Michigan; (3) Plaintiffs and members of the Damages Class were deprived of free and open competition; and (4) Plaintiffs and members of the Damages Class paid supra-competitive, artificially-inflated prices for opioid medication.

During the Class Period, Defendants' illegal conduct substantially affected Michigan

commerce.

As a direct and proximate result of Defendants' unlawful conduct, Plaintiffs and members of the Damages Class have been injured in their business and property and are threatened with further injury.

By reason of the foregoing, Defendants entered into agreements in restraint of trade in violation of Michigan Compiled Laws, §§ 445.771, *et seq*. Accordingly, Plaintiffs and members of the Damages Class seek all forms of relief available under Michigan Compiled Laws, §§ 445.771, *et seq*.

11) Minnesota: By reason of the foregoing, Defendants have violated Minnesota Statutes, §§ 325D.49, *et seq*. Plaintiffs on behalf of the Damages Class allege as follows:

Defendants' combination or conspiracy had the following effects: (1) price competition for opioid medication was restrained, suppressed, and eliminated throughout Minnesota; (2) prices for opioid medication were raised, fixed, maintained, and stabilized at artificially high levels throughout Minnesota; (3) Plaintiffs and members of the Damages Class were deprived of free and open competition; and (4) Plaintiffs and members of the Damages Class paid supra-competitive, artificially-inflated prices for opioid medication.

During the Class Period, Defendants' illegal conduct substantially affected Minnesota commerce.

As a direct and proximate result of Defendants' unlawful conduct, Plaintiffs and members of the Damages Class have been injured in their business and property and are threatened with further injury.

By reason of the foregoing, Defendants entered into agreements in restraint of trade in violation

of Minnesota Statutes, §§ 325D.49, *et seq*. Accordingly, Plaintiffs and members of the Damages Class seek all forms of relief available under Minnesota Statutes, §§ 325D.49, *et seq*.

12) Mississippi: By reason of the foregoing, Defendants have violated Mississippi Code, §§ 75-21-1, *et seq*. Plaintiffs on behalf of the Damages Class allege as follows:

Defendants' combination or conspiracy had the following effects: (1) price competition for opioid medication was restrained, suppressed, and eliminated throughout Mississippi; (2) prices for opioid medication were raised, fixed, maintained, and stabilized at artificially high levels throughout Mississippi; (3) Plaintiffs and members of the Damages Class were deprived of free and open competition; and (4) Plaintiffs and members of the Damages Class paid supra-competitive, artificially-inflated prices for opioid medication.

During the Class Period, Defendants' illegal conduct substantially affected Mississippi commerce.

As a direct and proximate result of Defendants' unlawful conduct, Plaintiffs and members of the Damages Class have been injured in their business and property and are threatened with further injury.

By reason of the foregoing, Defendants entered into agreements in restraint of trade in violation of Mississippi Code, §§ 75-21-1, *et seq*. Accordingly, Plaintiffs and members of the Damages Class seek all forms of relief available under Mississippi Code, §§ 75-21-1, *et seq*.

13) Nebraska: By reason of the foregoing, Defendants have violated Nebraska Revised Statutes, §§ 59-801, *et seq*. Plaintiffs on behalf of the Damages Class allege as follows:

Defendants' combination or conspiracy had the following effects: (1) price competition for

opioid medication was restrained, suppressed, and eliminated throughout Nebraska; (2) prices for opioid medication were raised, fixed, maintained, and stabilized at artificially high levels throughout Nebraska; (3) Plaintiffs and members of the Damages Class were deprived of free and open competition; and (4) Plaintiffs and members of the Damages Class paid supra-competitive, artificially-inflated prices for opioid medication.

During the Class Period, Defendants' illegal conduct substantially affected Nebraska commerce.

As a direct and proximate result of Defendants' unlawful conduct, Plaintiffs and members of the Damages Class have been injured in their business and property and are threatened with further injury.

By reason of the foregoing, Defendants entered into agreements in restraint of trade in violation of Nebraska Revised Statutes, §§ 59-801, *et seq*. Accordingly, Plaintiffs and members of the Damages Class seek all forms of relief available under Nebraska Revised Statutes, §§ 59-801, *et seq*.

14) Nevada: By reason of the foregoing, Defendants have violated Nevada Revised Statutes, §§ 598A.010, *et seq*. Plaintiffs on behalf of the Damages Class allege as follows:

Defendants' combination or conspiracy had the following effects: (1) price competition for opioid medication was restrained, suppressed, and eliminated throughout Nevada; (2) prices for opioid medication were raised, fixed, maintained, and stabilized at artificially high levels throughout Nevada; (3) Plaintiffs and members of the Damages Class were deprived of free and open competition; and (4) Plaintiffs and members of the Damages Class paid supra-competitive, artificially-inflated prices for opioid medication.

During the Class Period, Defendants' illegal conduct substantially affected Nevada commerce.

As a direct and proximate result of Defendants' unlawful conduct, Plaintiffs and members of the Damages Class have been injured in their business and property and are threatened with further injury.

By reason of the foregoing, Defendants entered into agreements in restraint of trade in violation of Nevada Revised Statutes, §§ 598A.010, *et seq*. Accordingly, Plaintiffs and members of the Damages Class seek all forms of relief available under Nevada Revised Statutes, §§ 598A.010, *et seq*.

15) New Hampshire: By reason of the foregoing, Defendants have violated New Hampshire Revised Statutes, §§ 356:1, *et seq*. Plaintiffs on behalf of the Damages Class allege as follows:

Defendants' combination or conspiracy had the following effects: (1) price competition for opioid medication was restrained, suppressed, and eliminated throughout New Hampshire; (2) prices for opioid medication were raised, fixed, maintained, and stabilized at artificially high levels throughout New Hampshire; (3) Plaintiffs and members of the Damages Class were deprived of free and open competition; and (4) Plaintiffs and members of the Damages Class paid supra-competitive, artificially-inflated prices for opioid medication.

During the Class Period, Defendants' illegal conduct substantially affected New Hampshire commerce.

As a direct and proximate result of Defendants' unlawful conduct, Plaintiffs and members of the Damages Class have been injured in their business and property and are threatened with further injury.

By reason of the foregoing, Defendants entered into agreements in restraint of trade in violation of New Hampshire Revised Statutes, §§ 356:1, *et seq*. Accordingly, Plaintiffs and members of the Damages Class seek all forms of relief available under New Hampshire Revised Statutes, §§ 356:1, *et seq*.

16) New Mexico: By reason of the foregoing, Defendants have violated New Mexico Statutes, §§ 57-1-1, *et seq*. Plaintiffs on behalf of the Damages Class allege as follows:

Defendants' combination or conspiracy had the following effects: (1) price competition for opioid medication was restrained, suppressed, and eliminated throughout New Mexico; (2) prices for opioid medication were raised, fixed, maintained, and stabilized at artificially high levels throughout New Mexico; (3) Plaintiffs and members of the Damages Class were deprived of free and open competition; and (4) Plaintiffs and members of the Damages Class paid supra-competitive, artificially-inflated prices for opioid medication.

During the Class Period, Defendants' illegal conduct substantially affected New Mexico commerce.

As a direct and proximate result of Defendants' unlawful conduct, Plaintiffs and members of the Damages Class have been injured in their business and property and are threatened with further injury.

By reason of the foregoing, Defendants entered into agreements in restraint of trade in violation of New Mexico Statutes, §§ 57-1-1, *et seq*. Accordingly, Plaintiffs and members of the Damages Class seek all forms of relief available under New Mexico Statutes, §§ 57-1-1, *et seq*.

17) New York: By reason of the foregoing, Defendants have violated New York General Business Laws, §§ 340, *et seq*. Plaintiffs on behalf of the Damages Class allege as

follows:

Defendants' combination or conspiracy had the following effects: (1) price competition for opioid medication was restrained, suppressed, and eliminated throughout New York; (2) prices for opioid medication were raised, fixed, maintained, and stabilized at artificially high levels throughout New York; (3) Plaintiffs and members of the Damages Class were deprived of free and open competition; and (4) Plaintiffs and members of the Damages Class paid supra-competitive, artificially-inflated prices for opioid medication.

During the Class Period, Defendants' illegal conduct substantially affected New York commerce.

As a direct and proximate result of Defendants' unlawful conduct, Plaintiffs and members of the Damages Class have been injured in their business and property and are threatened with further injury.

By reason of the foregoing, Defendants entered into agreements in restraint of trade in violation of New York General Business Laws, §§ 340, *et seq*. Accordingly, Plaintiffs and members of the Damages Class seek all forms of relief available under New York General Business Laws, §§ 340, *et seq*.

18) North Carolina: By reason of the foregoing, Defendants have violated North Carolina General Statutes, §§ 75-1, *et seq*. Plaintiffs on behalf of the Damages Class allege as follows:

Defendants' combination or conspiracy had the following effects: (1) price competition for opioid medication was restrained, suppressed, and eliminated throughout North Carolina; (2) prices for opioid medication were raised, fixed, maintained, and stabilized at artificially high

levels throughout North Carolina; (3) Plaintiffs and members of the Damages Class were deprived of free and open competition; and (4) Plaintiffs and members of the Damages Class paid supra-competitive, artificially-inflated prices for opioid medication.

During the Class Period, Defendants' illegal conduct substantially affected North Carolina commerce.

As a direct and proximate result of Defendants' unlawful conduct, Plaintiffs and members of the Damages Class have been injured in their business and property and are threatened with further injury.

By reason of the foregoing, Defendants entered into agreements in restraint of trade in violation of North Carolina General Statutes, §§ 75-1, *et seq*. Accordingly, Plaintiffs and members of the Damages Class seek all forms of relief available under North Carolina General Statutes, §§ 75-1, *et seq*.

19) North Dakota: By reason of the foregoing, Defendants have violated North Dakota Century Code, §§ 51-08.1-01, *et seq*. Plaintiffs on behalf of the Damages Class allege as follows:

Defendants' combination or conspiracy had the following effects: (1) price competition for opioid medication was restrained, suppressed, and eliminated throughout North Dakota; (2) prices for opioid medication were raised, fixed, maintained, and stabilized at artificially high levels throughout North Dakota; (3) Plaintiffs and members of the Damages Class were deprived of free and open competition; and (4) Plaintiffs and members of the Damages Class paid supra-competitive, artificially-inflated prices for opioid medication.

During the Class Period, Defendants' illegal conduct substantially affected North Dakota

commerce.

As a direct and proximate result of Defendants' unlawful conduct, Plaintiffs and members of the Damages Class have been injured in their business and property and are threatened with further injury.

By reason of the foregoing, Defendants entered into agreements in restraint of trade in violation of North Dakota Century Code, §§ 51-08.1-01, *et seq*. Accordingly, Plaintiffs and members of the Damages Class seek all forms of relief available under North Dakota Century Code, §§ 51-08.1-01, *et seq*.

20) Oregon: By reason of the foregoing, Defendants have violated Oregon Revised Statutes, §§ 646.705, *et seq*. Plaintiffs on behalf of the Damages Class allege as follows:

Defendants' combination or conspiracy had the following effects: (1) price competition for opioid medication was restrained, suppressed, and eliminated throughout Oregon; (2) prices for opioid medication were raised, fixed, maintained, and stabilized at artificially high levels throughout Oregon; (3) Plaintiffs and members of the Damages Class were deprived of free and open competition; and (4) Plaintiffs and members of the Damages Class paid supra-competitive, artificially-inflated prices for opioid medication.

During the Class Period, Defendants' illegal conduct substantially affected Oregon commerce.

As a direct and proximate result of Defendants' unlawful conduct, Plaintiffs and members of the Damages Class have been injured in their business and property and are threatened with further injury.

By reason of the foregoing, Defendants entered into agreements in restraint of trade in violation of Oregon Revised Statutes, §§ 646.705, *et seq*. Accordingly, Plaintiffs and members of the

Damages Class seek all forms of relief available under Oregon Revised Statutes, §§ 646.705, *et seq*.

21) South Dakota: By reason of the foregoing, Defendants have violated South Dakota Codified Laws, §§ 37-1-3.1, *et seq*. Plaintiffs on behalf of the Damages Class allege as follows:

Defendants' combination or conspiracy had the following effects: (1) price competition for opioid medication was restrained, suppressed, and eliminated throughout South Dakota; (2) prices for opioid medication were raised, fixed, maintained, and stabilized at artificially high levels throughout South Dakota; (3) Plaintiffs and members of the Damages Class were deprived of free and open competition; and (4) Plaintiffs and members of the Damages Class paid supra-competitive, artificially-inflated prices for opioid medication.

During the Class Period, Defendants' illegal conduct substantially affected South Dakota commerce.

As a direct and proximate result of Defendants' unlawful conduct, Plaintiffs and members of the Damages Class have been injured in their business and property and are threatened with further injury.

By reason of the foregoing, Defendants entered into agreements in restraint of trade in violation of South Dakota Codified Laws, §§ 37-1-3.1, *et seq*. Accordingly, Plaintiffs and members of the Damages Class seek all forms of relief available under South Dakota Codified Laws, §§ 37-1-3.1, *et seq*.

22) Tennessee: By reason of the foregoing, Defendants have violated Tennessee Code, §§ 47-25-101, *et seq*. Plaintiffs on behalf of the Damages Class allege as follows:

Defendants' combination or conspiracy had the following effects: (1) price competition for opioid medication was restrained, suppressed, and eliminated throughout Tennessee; (2) prices for opioid medication were raised, fixed, maintained, and stabilized at artificially high levels throughout Tennessee; (3) Plaintiffs and members of the Damages Class were deprived of free and open competition; and (4) Plaintiffs and members of the Damages Class paid supra-competitive, artificially-inflated prices for opioid medication.

During the Class Period, Defendants' illegal conduct substantially affected Tennessee commerce.

As a direct and proximate result of Defendants' unlawful conduct, Plaintiffs and members of the Damages Class have been injured in their business and property and are threatened with further injury.

By reason of the foregoing, Defendants entered into agreements in restraint of trade in violation of Tennessee Code, §§ 47-25-101, *et seq*. Accordingly, Plaintiffs and members of the Damages Class seek all forms of relief available under Tennessee Code,

§§ 47-25-101, *et seq*.

23) Utah: By reason of the foregoing, Defendants have violated Utah Code, §§ 76-10-3101, *et seq*. Plaintiffs on behalf of the Damages Class allege as follows:

Defendants' combination or conspiracy had the following effects: (1) price competition for opioid medication was restrained, suppressed, and eliminated throughout Utah; (2) prices for opioid medication were raised, fixed, maintained, and stabilized at artificially high levels throughout Utah; (3) Plaintiffs and members of the Damages Class were deprived of free and open competition; and (4) Plaintiff and members of the Damages Class paid supra-competitive,

artificially-inflated prices for opioid medication.

During the Class Period, Defendants' illegal conduct substantially affected Utah commerce.

As a direct and proximate result of Defendants' unlawful conduct, Plaintiffs and members of the Damages Class have been injured in their business and property and are threatened with further injury.

By reason of the foregoing, Defendants entered into agreements in restraint of trade in violation of Utah Code, §§ 76-10-3101, *et seq*. Accordingly, Plaintiffs and members of the Damages Class seek all forms of relief available under Utah Code, §§ 76-10- 3101, *et seq*.

24) Vermont: By reason of the foregoing, Defendants have violated Vermont Statutes, 9 V.S. §§ 2453, *et seq*. Plaintiffs on behalf of the Damages Class allege as follows:

Defendants' combination or conspiracy had the following effects: (1) price competition for opioid medication was restrained, suppressed, and eliminated throughout Vermont; (2) prices for opioid medication were raised, fixed, maintained, and stabilized at artificially high levels throughout Vermont; (3) Plaintiffs and members of the Damages Class were deprived of free and open competition; and (4) Plaintiffs and members of the Damages Class paid supra-competitive, artificially-inflated prices for opioid medication.

During the Class Period, Defendants' illegal conduct substantially affected Vermont commerce.

As a direct and proximate result of Defendants' unlawful conduct, Plaintiffs and members of the Damages Class have been injured in their business and property and are threatened with further injury.

By reason of the foregoing, Defendants entered into agreements in restraint of trade in violation of Vermont Statutes, 9 V.S. §§ 2453, *et seq*. Accordingly, Plaintiffs and members of the

Damages Class seek all forms of relief available under Vermont Statutes, 9 V.S. §§ 2453, *et seq*.

25) West Virginia: By reason of the foregoing, Defendants have violated West Virginia Code, §§ 47-18-1, *et seq*. Plaintiffs on behalf of the Damages Class allege as follows:

Defendants' combination or conspiracy had the following effects: (1) price competition for opioid medication was restrained, suppressed, and eliminated throughout West Virginia; (2) prices for opioid medication were raised, fixed, maintained, and stabilized at artificially high levels throughout West Virginia; (3) Plaintiffs and members of the Damages Class were deprived of free and open competition; and (4) Plaintiffs and members of the Damages Class paid supra-competitive, artificially-inflated prices for opioid medication.

During the Class Period, Defendants' illegal conduct substantially affected West Virginia commerce.

As a direct and proximate result of Defendants' unlawful conduct, Plaintiffs and members of the Damages Class have been injured in their business and property and are threatened with further injury.

By reason of the foregoing, Defendants entered into agreements in restraint of trade in violation of West Virginia Code, §§ 47-18-1, *et seq*. Accordingly, Plaintiffs and members of the Damages Class seek all forms of relief available under West Virginia Code, §§ 47-18-1, *et seq*.

26) Wisconsin: By reason of the foregoing, Defendants have violated Wisconsin Statutes, §§ 133.01*, et seq*. Plaintiffs on behalf of the Damages Class allege as follows:

Defendants' combination or conspiracy had the following effects: (1) price competition for

opioid medication was restrained, suppressed, and eliminated throughout Wisconsin; (2) prices for opioid medication were raised, fixed, maintained, and stabilized at artificially high levels throughout Wisconsin; (3) Plaintiffs and members of the Damages Class were deprived of free and open competition; and (4) Plaintiffs and members of the Damages Class paid supra-competitive, artificially-inflated prices for opioid medication.

During the Class Period, Defendants' illegal conduct substantially affected Wisconsin commerce.

As a direct and proximate result of Defendants' unlawful conduct, Plaintiffs and members of the Damages Class have been injured in their business and property and are threatened with further injury.

By reason of the foregoing, Defendants entered into agreements in restraint of trade in violation of Wisconsin Statutes, §§ 133.01*, et seq*. Accordingly, Plaintiffs and members of the Damages Class seek all forms of relief available under Wisconsin Statutes, §§ 133.01*, et seq*.

B. COUNT II- Violation Of State Consumer Protection Statutes (On Behalf of Plaintiffs and the Damages Class)

Plaintiffs incorporate and reallege, as though fully set forth herein, each of the paragraphs set forth above.

Defendants engaged in unfair competition or unfair, unconscionable, deceptive or fraudulent acts or practices in violation of the state consumer protection and unfair competition statutes listed below.

1) Arkansas: By reason of the foregoing, Defendants have violated the Arkansas Deceptive Trade Practices Act, Arkansas Code, §§ 4-88-101, *et. seq*. Plaintiffs on behalf of the

Damages Class allege as follows:

Defendants agreed to, and did in fact affect, fix, control, and/or maintain, at artificial and non-competitive levels, the prices at which opioid medication was sold, distributed, or obtained in Arkansas, and took efforts to conceal their agreements from Plaintiffs and members of the Damages Class. This conduct on the part of the Defendants constituted "deceptive" and "unconscionable" acts or practices in violation of Arkansas Code, § 4-88-107(a)(10).

Defendants' unlawful conduct had the following effects: (1) price competition opioid medication was restrained, suppressed, and eliminated throughout Arkansas; (2) prices for opioid medication were raised, fixed, maintained, and stabilized at artificially high levels throughout Arkansas; (3) Plaintiffs and the Damages Class were deprived of free and open competition; and (4) Plaintiffs and the Damages Class paid supra-competitive, artificially-inflated prices for opioid medication.

During the Class Period, Defendants' illegal conduct substantially affected Arkansas commerce and consumers.

As a direct and proximate result of Defendants' unlawful conduct, Plaintiffs and the Damages Class have been injured and are threatened with further injury.

Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Arkansas Code, §§ 4-88-101, *et. seq.*, and, accordingly, Plaintiffs and the Damages Class seek all relief available under that statute.

2) California: By reason of the foregoing, Defendants have violated California's Unfair Competition Law, California Business and Professions Code, §§ 17200, *et seq*. Plaintiffs on behalf of the Damages Class allege as follows:

Defendants committed acts of unfair competition, as defined by Section 17200, *et seq*., by engaging in a conspiracy to fix and stabilize the price of opioid medication as described above.

The acts, omissions, misrepresentations, practices and non-disclosures of Defendants, as described above, constitute a common and continuing course of conduct of unfair competition by means of unfair, unlawful and/or fraudulent business acts or practices within the meaning of Section 17200, *et seq*., including, but not limited to: (1) violations of the Cartwright Act, California Business and Professions Code, §§ 16720, *et seq*., as set forth above.

Defendants' acts, omissions, misrepresentations, practices and nondisclosures are unfair, unconscionable, unlawful and/or fraudulent independently of whether they constitute a violation of the Cartwright Act.

Defendants' acts or practices are fraudulent or deceptive within the meaning of Section 17200, *et seq*.

Defendants' conduct was carried out, effectuated, and perfected within the State of California. Defendants maintained offices in California where their employees engaged in communications, meetings, and other activities in furtherance of Defendants' conspiracy.

By reason of the foregoing, Plaintiffs and the Damages Class are entitled to full restitution and/or disgorgement of all revenues, earnings, profits, compensation, and benefits that may have been obtained by Defendants as result of such business acts and practices described above.

Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of California Business and Professions Code, §§ 17200, *et seq.*, and, accordingly, Plaintiffs and the Damages Class seek all relief available under that statute.

3) Florida: By reason of the foregoing, Defendants have violated the Florida Deceptive and

Unfair Trade Practices Act, Florida Statues, §§ 501.201, *et seq*. Plaintiffs on behalf of the Damages Class allege as follows:

4) Defendants' unlawful conduct had the following effects: (1) price competition for opioid medication was restrained, suppressed, and eliminated throughout Florida; (2) prices for opioid medication were raised, fixed, maintained, and stabilized at artificially high levels throughout Florida; (3) Plaintiffs and the Damages Class were deprived of free and open competition; and (4) Plaintiffs and the Damages Class paid supra-competitive, artificially-inflated prices for opioid medication.

During the Class Period, Defendants' illegal conduct substantially affected Florida commerce and consumers.

As a direct and proximate result of Defendants' unlawful conduct, Plaintiffs and the Damages Class have been injured and are threatened with further injury.

Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Florida Statutes, §§ 501.201, *et seq.*, and, accordingly, Plaintiffs and the Damages Class seek all relief available under that statute.

5) Hawaii: By reason of the foregoing, Defendants have violated Hawaii Revised Statutes, § 480-2. Plaintiffs on behalf of the Damages Class allege as follows:

Defendants' unlawful conduct had the following effects: (1) price competition for opioid medication was restrained, suppressed, and eliminated throughout Hawaii; (2) prices for opioid medication were raised, fixed, maintained, and stabilized at artificially high levels throughout Hawaii; (3) Plaintiffs and the Damages Class were deprived of free and open competition; and (4) Plaintiffs and the Damages Class paid supra-competitive, artificially-inflated prices for

opioid medication.

During the Class Period, Defendants' illegal conduct substantially affected Hawaii commerce and consumers.

As a direct and proximate result of Defendants' unlawful conduct, Plaintiffs and the Damages Class have been injured and are threatened with further injury.

Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Hawaii Revised Statutes, § 480-2, and, accordingly, Plaintiffs and the Damages Class seek all relief available under that statute.

6) Massachusetts: By reason of the foregoing, Defendants have violated the Massachusetts Consumer and Business Protection Act, M.G.L. c. 93A, § 1, *et seq*. Plaintiffs on behalf of the Damages Class allege as follows:

Defendants' unlawful conduct had the following effects: (1) price competition for opioid medication was restrained, suppressed, and eliminated throughout Massachusetts; (2) prices for opioid medication were raised, fixed, maintained, and stabilized at artificially high levels throughout Massachusetts; (3) Plaintiffs and the Damages Class were deprived of free and open competition; and (4) Plaintiffs and the Damages Class paid supra-competitive, artificially-inflated prices for opioid medication.

During the Class Period, Defendants marketed, sold, or distributed opioid medication in Massachusetts, and Defendants' illegal conduct substantially affected Massachusetts commerce and consumers.

As a direct and proximate result of Defendants' unlawful conduct, Plaintiffs and the Damages Class have been injured and are threatened with further injury.

Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of M.G.L. c. 93A, § 2 and, accordingly, Plaintiffs and the Damages Class seek all relief available under that statute.

Each of the Defendants or their representatives have been served with a demand letter in accordance with M.G.L. c. 93A, § 1, or such service of a demand letter was unnecessary due to the defendant not maintaining a place of business within the Commonwealth of Massachusetts or not keeping assets within the Commonwealth. More than thirty days has passed since such demand letters were served, and each Defendant served has failed to make a reasonable settlement offer.

By reason of the foregoing, Defendants engaged in unfair competition and unfair or deceptive acts or practices, in violation of M.G.L. c. 93A, § 2. Defendants' violations of Chapter 93A were knowing or willful, entitling Plaintiffs and the Damages Class to multiple damages.

7) Missouri: By reason of the foregoing, Defendants have violated Missouri's Merchandising Practices Act, specifically Mo. Rev. Stat. § 407.020. Plaintiffs on behalf of the Damages Class allege as follows:

Defendants' unlawful conduct had the following effects: (1) price competition for opioid medication was restrained, suppressed, and eliminated throughout Missouri; (2) prices for opioid medication were raised, fixed, maintained, and stabilized at artificially high levels throughout Missouri; (3) Plaintiffs and the Damages Class were deprived of free and open competition; and (4) Plaintiffs and the Damages Class paid supra-competitive, artificially-inflated prices for opioid medication.

During the Class Period, Defendants marketed, sold, or distributed opioid medication in

Missouri, and Defendants' illegal conduct substantially affected Missouri commerce and consumers.

As a direct and proximate result of Defendants' unlawful conduct, Plaintiffs and the Damages Class have been injured and are threatened with further injury.

Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Missouri's Merchandising Practices Act, specifically Mo. Rev. Stat. § 407.020, which prohibits "the act, use or employment by any person of any deception, fraud, false pretense, false promise, misrepresentation, unfair practice or the concealment, suppression, or omission of any material fact in connection with the sale or advertisement of any merchandise in trade or commerce," as further interpreted by Missouri Code of State Regulations, 15 CSR 60-7.010, *et seq*., 15 CSR 60-8.010, *et seq*., and 15 CSR 60-9.010, *et seq*., and Mo. Rev. Stat. § 407.025, which provides for the relief sought in this count.

8) Montana: By reason of the foregoing, Defendants have violated the Montana Unfair Trade Practices and Consumer Protection Act of 1973, Montana Code, §§ 30-14-101, *et seq*. and §§ 30-14-201, *et seq*. Plaintiffs on behalf of the Damages Class allege as follows:

Defendants' unlawful conduct had the following effects: (1) price competition for opioid medication was restrained, suppressed, and eliminated throughout Montana; (2) prices for opioid medication were raised, fixed, maintained, and stabilized at artificially high levels throughout Montana; (3) Plaintiffs and the Damages Class were deprived of free and open competition; and (4) Plaintiffs and the Damages Class paid supra-competitive, artificially-inflated prices for opioid medication.

During the Class Period, Defendants marketed, sold, or distributed opioid medication in Montana, and Defendants' illegal conduct substantially affected Montana commerce and consumers.

As a direct and proximate result of Defendants' unlawful conduct, Plaintiffs and the Damages Class have been injured and are threatened with further injury.

Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Montana Code, §§ 30-14-101, *et seq*. and §§ 30-14-201, *et seq.*, and, accordingly, Plaintiffs and the Damages Class seek all relief available under that statute.

9) Nebraska: By reason of the foregoing, Defendants have violated Nebraska's Consumer Protection Act, Nebraska Revised Statues, §§ 59-1601, *et seq*. Plaintiffs on behalf of the Damages Class allege as follows:

Defendants' unlawful conduct had the following effects: (1) opioid medication price competition was restrained, suppressed, and eliminated throughout Nebraska; (2) opioid medication prices were raised, fixed, maintained, and stabilized at artificially high levels throughout Nebraska; (3) Plaintiffs and the Damages Class were deprived of free and open competition; and (4) Plaintiffs and the Damages Class paid supra-competitive, artificially-inflated prices for opioid medication.

During the Class Period, Defendants' illegal conduct substantially affected Nebraska commerce and consumers.

As a direct and proximate result of Defendants' unlawful conduct, Plaintiffs and the Damages Class have been injured and are threatened with further injury.

Defendants' actions and conspiracy have had a substantial impact on the public interests of

Nebraska and its residents.

Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Nebraska's Consumer Protection Act, Nebraska Revised Statues, §§ 59-1601, *et seq*., and, accordingly, Plaintiffs and the Damages Class seek all relief available under that statute.

10) New Mexico: By reason of the foregoing, Defendants have violated the New Mexico Unfair Practices Act, New Mexico Statutes, § 57-12-1, *et seq*. Plaintiffs on behalf of the Damages Class allege as follows:

Defendants agreed to, and did in fact affect, fix, control, and/or maintain, at artificial and non-competitive levels, the prices at which opioid medication was sold, distributed, or obtained in New Mexico. Defendants took efforts to conceal their agreements from Plaintiffs and members of the Damages Class. This conduct on the part of the Defendants constituted "unfair or deceptive trade practices and unconscionable trade practices" in violation of New Mexico Statutes, § 57-12-3.

Defendants and their co-conspirators possessed the sole power to set prices of opioid medication, and used this power to conceal their price-fixing conspiracy from Plaintiffs and members of the Damages Class. Defendants took advantage of Plaintiffs' and members of the Damages Class' lack of knowledge to a grossly unfair degree, within the meaning of New Mexico Statutes, § 57-12-2(E).

Defendants' unlawful conduct had the following effects: (1) price competition for opioid medication was restrained, suppressed, and eliminated throughout New Mexico; (2) prices for opioid medication were raised, fixed, maintained, and stabilized at artificially high levels

throughout New Mexico; (3) Plaintiffs and the Damages Class were deprived of free and open competition; and (4) Plaintiffs and the Damages Class paid supra-competitive, artificially-inflated prices for opioid medication.

During the Class Period, Defendants' illegal conduct substantially affected New Mexico commerce and consumers.

As a direct and proximate result of Defendants' unlawful conduct, Plaintiffs and the Damages Class have been injured and are threatened with further injury.

Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of New Mexico Statutes, § 57-12-1, *et seq.*, and, accordingly, Plaintiffs and the Damages Class seek all relief available under that statute.

11) New York: By reason of the foregoing, Defendants have violated New York General Business Laws, § 349, *et seq*. Plaintiffs on behalf of the Damages Class allege as follows:

Defendants agreed to, and did in fact, act in restraint of trade or commerce by affecting, fixing, controlling and/or maintaining, at artificial and noncompetitive levels, the prices at which opioid medication was sold, distributed or obtained in New York and took efforts to conceal their agreements from Plaintiffs and the Damages Class.

The conduct of the Defendants described herein constitutes consumer- oriented deceptive acts or practices within the meaning of New York General Business Laws,

§ 349, which resulted in consumer injury and broad adverse impact on the public at large, and harmed the public interest of New York State in an honest marketplace in which economic activity is conducted in a competitive manner.

Defendants made certain statements about opioid medication that they knew would be seen by New York residents and these statements either omitted material information that rendered the statements they made materially misleading or affirmatively misrepresented the real cause of price increases for opioid medication.

Defendants' unlawful conduct had the following effects: (1) opioid medication price competition was restrained, suppressed, and eliminated throughout New York; (2) opioid medication prices were raised, fixed, maintained, and stabilized at artificially high levels throughout New York; (3) Plaintiffs and the Damages Class were deprived of free and open competition; and (4) Plaintiffs and the Damages Class paid supra-competitive, artificially-inflated prices for opioid medication.

During the Class Period, Defendants' illegal conduct substantially affected New York commerce and consumers.

During the Class Period, each of the Defendants named herein, directly, or indirectly and through affiliates they dominated and controlled, manufactured, sold and/or distributed opioid medication in New York.

Plaintiffs and members of the Damages Class seek all relief available pursuant to New York General Business Laws, § 349(h).

12) North Carolina: By reason of the foregoing, Defendants have violated North Carolina General Statutes, §§ 75-1.1, *et seq*. Plaintiffs on behalf of the Damages Class allege as follows:

Defendants agreed to, and did in fact affect, fix, control, and/or maintain, at artificial and non-competitive levels, the prices at which opioid medication was sold, distributed, or obtained in

North Carolina. Defendants took efforts to conceal their agreements from Plaintiffs and members of the Damages Class. Defendants and their co-conspirators possessed the sole power to set prices of opioid medication, and used this power to conceal their price-fixing conspiracy from Plaintiffs and members of the Damages Class. Plaintiffs and members of the Damages Class were therefore unaware that they were being unfairly and illegally overcharged for opioid medication.

Defendants' unlawful conduct had the following effects: (1) price competition for opioid medication was restrained, suppressed, and eliminated throughout North Carolina; (2) prices for opioid medication were raised, fixed, maintained, and stabilized at artificially high levels throughout North Carolina; (3) Plaintiffs and the Damages Class were deprived of free and open competition; and (4) Plaintiffs and the Damages Class paid supra-competitive, artificially-inflated prices for opioid medication.

During the Class Period, Defendants marketed, sold, or distributed opioid medication in North Carolina, and Defendants' illegal conduct substantially affected North Carolina commerce and consumers.

As a direct and proximate result of Defendants' unlawful conduct, Plaintiffs and the Damages Class have been injured and are threatened with further injury.

Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of North Carolina General Statutes, §§ 75-1.1, *et seq.*, and, accordingly, Plaintiffs and the Damages Class seek all relief available under that statute.

13) Tennessee: Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Tennessee General Statutes, §§ 47-18-104, *et seq*.

14) Vermont: By reason of the foregoing, Defendants have violated the Vermont Consumer Protection Act, 9 Vermont Statutes, §§ 2453, *et seq*. Plaintiffs on behalf of the Damages Class allege as follows:

Defendants agreed to, and did in fact affect, fix, control, and/or maintain, at artificial and non-competitive levels, the prices at which opioid medication was sold, distributed, or obtained in Vermont. Defendants took efforts to conceal their agreements from Plaintiffs and members of the Damages Class, including through affirmative misrepresentations and omissions of information important to Plaintiffs and members of the Damages Class.

Defendants and their co-conspirators possessed the sole power to set prices of opioid medication, and used this power to conceal their price-fixing conspiracy from Plaintiffs and members of the Damages Class. Plaintiffs and members of the Damages Class were therefore unaware that they were being unfairly and illegally overcharged for opioid medication.

Defendants' unlawful conduct had the following effects: (1) price competition for opioid medication was restrained, suppressed, and eliminated throughout Vermont; (2) prices for opioid medication were raised, fixed, maintained, and stabilized at artificially high levels throughout Vermont; (3) Plaintiffs and the Damages Class were deprived of free and open competition; and (4) Plaintiffs and the Damages Class paid supra-competitive, artificially-inflated prices for opioid medication. During the Class Period, Defendants' illegal conduct substantially affected Vermont commerce and consumers.

As a direct and proximate result of Defendants' unlawful conduct, Plaintiffs and the Damages Class have been injured and are threatened with further injury.

Defendants have engaged in unfair competition or unfair or deceptive acts or practices in

violation of 9 Vermont Statutes, §§ 2453, *et seq.*, and, accordingly, Plaintiffs and the Damages Class seek all relief available under that statute.

C. COUNT III- UNJUST ENRICHMENT(On Behalf of Plaintiff and the Damages Class)

Plaintiff incorporates and realleges, as though fully set forth herein, each of the paragraphs set forth above and demands damages that they show themselves entitled in each of the above-described states or jurisdictions due to the doctrine of unjust enrichment.

As a result of their unlawful conduct described above, Defendants have and will continue to be unjustly enriched by the receipt of unlawfully and artificially-inflated prices for generic enoxaparin.

Defendants have benefited from their unlawful conduct described above. It would be inequitable for Defendants to be permitted to retain any of the ill-gotten gains resulting from the overpayments made by Plaintiffs and members of the Damages Class for generic enoxaparin manufactured by Defendants during the Class Period.

Plaintiffs and members of the Damages Class are entitled to the amount of Defendants' ill-gotten gains resulting from their unlawful, unjust, and inequitable conduct. Plaintiffs and members of the Damages Class are therefore entitled to the establishment of a constructive trust consisting of all ill-gotten gains from which Plaintiffs and members of the Damages Class may make claims on a *pro rata* basis.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs and Class members pray for relief as set forth below:

1. Certification of the action as a class action pursuant to Federal Rule of Civil Procedure

23, and appointment of Plaintiffs as Class Representatives and their counsel of record as Class Counsel;

2. A declaration that Defendants' conduct constituted: (1) an unlawful restraint of trade in violation of the federal and state statutes cited herein; and (2) unfair competition or unfair, unconscionable, deceptive or fraudulent acts or practices in violation of the state consumer protection and unfair competition statutes cited herein;

3. That Defendants were unjustly enriched;

4. Restitution and/or damages to members of the Damages Class, for their purchases of opioid medication;

5. Actual damages, statutory damages, punitive or treble damages, and such other relief as provided by the statutes cited herein; Pre-judgment and post-judgment interest on such monetary relief;

6. The costs of bringing this suit, including reasonable attorneys' fees; and All other relief to which Plaintiffs and the members of the Classes may be entitled at law or in equity.

DEMAND FOR JURY TRIAL

Pursuant to Federal Rule of Civil Procedure 38, Plaintiffs hereby demand a trial by jury on their claims.

Dated: October 3, 2019

Respectfully submitted,

/s/ Gordon Ball

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